alza

ENVIRONMENTAL ASSESSMENT

TYPE 1 - PROPOSED FOOD ADDITIVE APPROVAL
PRODUCT: DURA SE®-120

1. Date: 6 May 1988

2. Name of Applicant(s): Schering Corporation
ALZA Corporation

3. Address(es): Schering Corporation
2000 Galloping Hill Road
Kenilworth, NJ 07033

ALZA Corporation
950 Page Mill Road
Palo Alto, CA 94303

4. Description of Proposed Action:

The proposed action is approval of the Food Additive Petition (FAP) for Dura Se®-120. The petition proposes that the current food additive regulation 573.920 Selenium be amended to allow for the safe use of a 4-month controlled release sodium selenite (Dura Se®-120) bolus which is designed to provide cattle 3.0 milligrams per head per day as a nutritional supplement. The petition is needed in order to make available this nutritional supplement for dairy and beef cattle/calves with selenium deficiency or in selenium deficient areas.

The product will be manufactured, packaged and labeled for Schering Corporation by ALZA Corporation at their Palo Alto, CA facility. This plant is located in the Stanford Industrial Park, a short distance south of Stanford University. The area is zoned Industrial and is primarily occupied by research oriented light industrial firms. A residential neighborhood is located a block away and major building and site improvements have to receive approval from an Architectural Review Committee. The finished product is intended for distribution throughout selenium deficient areas of the United States and in other countries where approved for sale. The product will be distributed by Schering Corporation out of their Omaha, NE distribution center.

5. Identification of Chemical Substance:

Active ingredient is Selenium delivered as Sodium Selenite.

Molecular Weight: 172.95

Formula: Na_2O_3Se; Na 26.59% O 27.75% Se 45.65%

Appearance: White, tetragonal crystals

CAS Registration Number: 10102-18-8

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6. Introduction of Substances into the Environment:

The following substances may be emitted in the process of manufacturing:

Formulation components (Appendix A)
Defective or damaged dosage systems
Trace amounts of solvent (n-heptane) used for cleaning

The applicable Federal, State and Local emission regulations for the Palo Alto Plant are:

Federal Clean Air Act
Federal Resource Conservation and Recovery Act (RCRA)
State of California Hazardous Waste Control Law
Bay Area Air Quality Management District Regulations
San Francisco Regional Water Quality Control Board
City of Palo Alto Sewer Use Ordinance

The plant is in compliance with the applicable emission requirements.

Approval of the FAP will have no adverse effect upon compliance with current emissions regulations at the Palo Alto Plant.

The published regulation 21 CFR 573.920 Selenium allows for the safe use of the food additive selenium in cattle, not to exceed the maximum level of 3 milligrams per head per day.

In support of this regulation, the potential environmental impacts associated with selenium feed supplementation up to a level of 3 mg/hd/day in dairy and beef cattle, as well as in other species e.g. poultry, swine and sheep, were thoroughly investigated by The American Feed Industry Association (AFIA) in an Environmental Impact Analysis Report dated January 10, 1986. The Center for Veterinary Medicine, based on review of this EIAR coupled with further scientific documentation, concluded that selenium supplementation via animal feeds and salt-mineral mixes at the levels published in 21 CFR 573.920 for various animal species, will not have a significant effect on the quality of the human environment (FONSI Statement, Zeeman et al, December 1, 1986). The EIAR prepared by the AFIA and the FONSI statement prepared by the CVM are found as Attachment I to this document.

Dura Se®-120 is a sustained released bolus which contains 360 milligrams of the food additive selenium (as sodium selenite) and provides cattle with daily supplementation at a level of 3 milligrams per head per day. The bolus is inherently physically durable and is composed of an injection molded capsule which serves as a semipermeable membrane, a solid osmotic tablet, a partition layer, a wax/ selenium supplement layer, and an iron plug with an exit port, all tightly assembled.

This delivery system is based on a Push-Melt osmotic pump technology designed to deliver selenium at a zero order rate for prolonged periods. This maximizes reproducibility and reliability of selenium supplementation. Functionality studies conducted in fistulated cattle demonstrate and confirm that the Dura Se®-120 bolus operates to provide 3 mg selenium per head per day in a uniform and controlled manner as predicted by in vitro

release studies. Following bolus administration, the start-up period of selenium release begins in Week 1, and steady-state functioning is achieved by Week 3 where selenium is released at approximately 3 mg/day. The bolus continues to release selenium to a crisp shut down, when the dose is exhausted. Assays of the spent boluses reveal that only trace amounts of selenium, 0.4 mg Se/bolus or 0.11% of dose, remain in the bolus.

The functionality and effectiveness of Dura Se®-120 have also been fully tested and confirmed under field conditions in selenium deficient cattle.

Dura Se®-120 is targeted for use in selenium deficient dairy and beef cattle or in selenium deficient areas of the United States (Attachment II). USDA estimates for total dairy and beef cattle, inventory and slaughter, in 1987 were 137.8 million head (USDA, Livestock and Poultry Situation and Outlook Report, February 1988, page 9). Dura Se®-120 will be utilized specifically in dairy heifers, pregnant beef cows and beef calves/stockers. Primary usage is expected in animals where selenium supplementation in feed is not possible (i.e. grazing cattle) or where mineral-salt mixtures, injectable selenium products, or selenium pellets are currently used.

This target market segment constitutes approximately 14% of the total dairy/beef market, i.e. 19.0 million head/137.8 million head. We predict that the maximum growth for Dura Se®-120 in this market segment is 21% total market share or approximately 4.0 million head (4.0 million boluses) per annum. On a worst case basis, assuming all selenium administered to cattle equals selenium entering the environment via animal wastes, 4.0 million boluses, each containing 360 mg selenium, would amount to roughly 1.5 metric tons of selenium entering the environment on an annual basis.

In comparison to figures supplied in the selenium EIAR prepared by AFIA in 1986 (Section D.6), this worst case figure amounts to less than 3% of the total 45.2 metric tons of selenium predicted to enter the environment annually directly due to feed supplementation - all species - in the United States (1979). Further, this same figure represents less than 0.25% of the total 618 metric tons of selenium utilized in the U.S. as a whole during the same year.

No adverse environmental impact is expected from this incremental additional use of supplemental selenium in dairy and beef cattle.

In summary, the Dura Se®-120 bolus is a self-contained, durable system which allows for the safe administration and delivery of the food additive selenium to cattle. The product is designed and functions within the limits set forth in 21 CFR 573.920. Dura Se®-120 provides a more consistent means of selenium supplementation than do "feeds" or salt-mineral mixes because appetite food consumption does not play a role in daily intake. Therefore, in accordance with the published regulation and previously referenced supportive documents, no significant amounts of selenium will enter air, marine or terrestrial ecosystems as a result of the use of the product.

7. Fate of Substances Emitted into the Environment:

ALZA is registered with the EPA as a waste generator (EPA Reg. No. CAD049231541). All selenium waste generated in the product manufacture is transferred from the Pilot Plant to a permitted waste staging facility. It is placed in

disposal containers by trained hazardous waste technicians and held for removal by a licensed waste hauler to either an EPA permitted Class I landfill or approved incinerator. Non-hazardous items (spent air filters, solids from formulation components, used cleaning implements, waste paper from packaging and labeling) will be drummed for disposal in approved landfills or by incineration, as necessary.

Once product enters the marketplace, a program sponsored directly by Schering Corporation is in place for even exchange of outdated or damaged delivery systems for dated or intact goods. Outdated or damaged systems are returned to the Omaha, NE distribution center for disposal. All systems are placed in disposal containers and held for removal by a licensed waste hauler to either an EPA permitted Class I landfill or approved incinerator.

The environmental fate of selenium following supplementation to cattle at a rate of 3 mg/hd/day is thoroughly addressed in the 1986 FONSI statement previously referenced and found as ATTACHMENT I to this report.

8. Environmental Effects of Released Substances:

Trace amounts of solvent will be emitted into the air, in accordance with applicable environmental regulations. The solvent will be at negligible concentration in the air stream. Landfilling of the non-hazardous components such as paper will not release significant quantities of harmful compounds into the ground.

The environmental effects of selenium on terrestrial and aquatic ecosystems as a result of selenium supplementation to cattle at a rate of 3 mg/hd/day, are thoroughly addressed in the 1986 FONSI statement previously referenced and found as ATTACHMENT I to this report.

9. Use of Resources and Energy:

There will be minimum depletion of natural resources used to manufacture components of this system. Energy will be used in the operation of the equipment.

There will be no effect on any endangered species.

There will be no effect on any property listed in the National Register of Historic Places.

10. Mitigation Measures:

The handling measures outlined herein have been implemented as a measure to mitigate the effect of this production process on the environment. No further measure is required.

The entire production operation will be carried out under the supervision of qualified personnel, with training provided for normal and emergency operations. ALZA employees who will be working with the dosage form receive training in general safety and chemical handling techniques. ALZA has a computerized MSDS (Material Safety Data Sheet) system which provides employees immediate access to chemical safety information. Employees also receive training in the specific hazards of each chemical with which they

work. Selenium-specific training information is summarized in Attachment III. Spill control protection is provided in all areas where chemicals are handled. ALZA is in compliance with the local Hazardous Material Storage Ordinance and is in the process of developing a Sara III plan. ALZA does not have an NPDES permit but, as noted in Section 6, is fully permitted by the regional Bay Area Air Quality Management District and all other applicable regulatory agencies.

11. Alternative to Proposed Action:

The alternative to the approval of the FAP is to prevent this nutritional supplement from being available to the dairy and beef industries.

12. List of Preparers:

Douglas S. Burhyte, Manager, Process Engineering, ALZA Corporation
David Breuer, Senior Environmental Engineer, Corporate Engineering, Schering Corporation

13. Certification

The undersigned official certifies that the information is true, accurate, and complete to the best knowledge of the firm or agency responsible for preparation of the environmental assessment.

5/17/88
Date

Signature of Responsible Official

V.P. MFG
Title

ATTACHMENT I

- FONSI Statement, CVM, December 1986
- EIAR, AFIA, January 1986
- EA, AFMA, April, 1981

FINDING OF NO SIGNIFICANT IMPACT

for

Selenium Supplementation of Animal Feeds

FAP 2201

The American Feed Industry Association, Inc.

The Center for Veterinary Medicine has carefully considered the potential environmental impact of this action and has concluded that this action will not have a significant effect on the quality of the human environment and that an environmental impact statement therefore will not be prepared.

The American Feed Industry Association, Inc. [AFIA, previously the American Feed Manufacturers Association, Inc. (AFMA)] of Arlington, Virginia has filed a food additive petition (FAP 2201) with the Food and Drug Administration (FDA) that proposes that the selenium levels used in animal feeds as a nutritional supplement be increased to a uniform 0.3 mg of selenium per kilogram of animal feed. The FDA published a notice in the Federal Register (51 FR 6321, February 21, 1986) that this petition had been filed. The FDA has decided to grant this increased use of selenium. Specific limitations on the use of selenium in animal feeds are stated in the regulation approving this food additive petition.

The AFIA claims that selenium has been found to be an essential nutrient for most animals and that most animal feeds in the United States are apparently deficient in this element. The AFIA proposes that the maximum level of selenium supplementation of the animal feeds for most species of food-producing animals shall not exceed 0.3 ppm (parts per million) on a complete feed or ration basis, and shall not exceed 3 mg/head/day for cattle or 0.7 mg/head/day for sheep when selenium is given in a salt-mineral mix.

An Environmental Impact Analysis Report (EIAR, dated January 10, 1986) that examines the potential environmental impacts of approving this petition has been prepared by AFIA and is attached to this Finding of No Significant Impact (FONSI). Previous environmental documents have already evaluated the potential impacts associated with allowing selenium supplementation of the diets of several animal species grown for human food. These other publicly available environmental documents consist of: 1) an EIAR (July 26, 1972) and an Environmental Impact Statement (January 8, 1974) for selenium supplementation of the diets of chickens, turkeys, and swine; 2) an EIAR (August 26, 1976) and three Environmental Assessment Reports (November 21, 1977, June 6, 1978, and November 20, 1978) for selenium supplementation of the diets of ruminants (sheep, beef cattle, and dairy cattle); 3) an EIAR (March 13, 1981) for selenium supplementation of the diet of ducks; 4) an Environmental Assessment (EA, dated April 24, 1981) for the addition of selenium to the feed of laying hens; and 5) an EA (June 1, 1981) for an increase in the supplementation level of selenium in the diet of weanling swine.

Until now, the EA prepared for laying hens (Zeeman and Boyd, 1981) included the most comprehensive evaluation of potential environmental introductions, environmental fate and environmental effects of selenium in animal diets. Therefore, a copy of that EA was included as part of the EIAR for FAP 2201 and has also been attached to this FONSI.

The AFIA's 1986 EIAR lists the currently approved selenium supplementation levels in the feed of several food-producing animal species. The current levels of selenium feed supplementation range from 0.1 to 0.3 ppm on a complete feed basis. The proposed maximum level in the feed is a uniform 0.3 ppm (0.3 mg of selenium per kg of complete feed).

The EIAR states that the proposed new practice of selenium supplementation is estimated to result in a doubling of the current levels of selenium used for feed supplementation, or an additional 22.6 metric tons of selenium per year being introduced into the U.S. environment. This figure of 22.6 metric tons would appear to have been taken from the 1981 EA prepared for laying hens, which attempted to estimate the selenium environmental introductions resulting from the supplementation of the feeds of major food-producing animals only. The levels of selenium being introduced into the environment from the supplementation of the feeds of minor species of food-producing animals and of non-food animals has not been estimated. The figure of 22.6 metric tons of selenium per year also does not reflect subsequently approved increases in selenium supplementation of duck and weanling swine diets.

Background

The scientific literature (to 1980) describing the potential environmental effects of selenium supplementation of animal diets was referenced in the 1981 EA for laying hens (Zeeman and Boyd, 1981). Several reviews and pertinent additional scientific references on selenium in the environment have been published recently (see References). This background information has been used in this FONSI to augment the 1981 EA evaluation of the following issues:

1. Increased environmental introductions of selenium as a result of increasing the level of selenium supplementation in animal feeds.

2. Probable environmental distribution (fate) of selenium entering the environment from this use of selenium supplemented feeds.

3. Possible effects of the selenium distributed throughout the environment upon the organisms living in those environments.

Since the EA of 1981 (Zeeman and Boyd, 1981), a considerable body of new data on the environmental introduction, fate, and effects of selenium has been published. A review of this scientific data has resulted in a refinement of the levels of selenium that are likely to occur in various components of the environment and that are likely to be of concern in the

aquatic environment. In addition, considerable scientific disagreement continues concerning the degree of selenium bioconcentration and bioaccumulation that is likely to occur in organisms in the environment and the significance of any such accumulation. These concerns are also briefly reviewed below. Note however, that the review of these concerns has not resulted in an appreciable change in the conclusion made in the 1981 EA for laying hens.

Environmental Introductions

The 1981 EA by Zeeman and Boyd basically reviewed the environmental consequences that could result from the use 0.1 mg selenium/kg of complete feed given to laying hens. In the 1981 EA, the increased environmental introductions of selenium were considered from both a broad (i.e., nationwide) and a local context. Both of these types of estimates are revised below to account for a) the additional scientific information currently available and, b) the additional environmental introductions expected from an increased level of selenium supplementation of animal diets.

Broad Context:

Worldwide soil erosion and weathering of rocks are reported to carry downstream each year about 10,000 metric tons of selenium to the sea (Adams and Johnson, 1981; Fishbein, 1983; Hodson et al., 1984). Eisler (1985) reports that, additionally, about 4,600 metric tons of selenium are released into the U.S. environment annually, with 33% coming from fossil fuel combustion, 59% from industrial losses, and 8% from municipal wastes. Adams and Johnson (1981) report that the total U.S. air emissions and solid waste disposal of selenium are estimated, respectively, to be about 11,000 and 31,000 metric tons/yr.

The intentional production of selenium comes primarily from the refining of copper and the Western World selenium production averaged almost 1,000 metric tons/yr from 1964 to 1973 (Fishbein, 1983) and over 1,400 metric tons/yr from 1979 to 1983 (Manser, 1984). Selenium production levels for 1984 were projected to be over 1,400 metric tons (Fishbein, 1983; Manser, 1984). This selenium is used predominantly in the electronics, plastics and glass industries. Manser (1984) says that the agricultural uses of selenium (in animal feeds, in fertilizers, etc.) account for less than 10% of the consumption of selenium produced in the Western world.

The production of selenium in the U.S. from 1979 to 1983 averaged over 250 metric tons/yr and was projected to remain at that level in 1984 (Manser, 1984). The consumption of selenium in the U.S. increased from about 400 metric tons in 1977 to over 650 metric tons in 1983 (Manser, 1984). The bulk of the difference between U.S. production and consumption of selenium is made up for by importing selenium compounds into the U.S., primarily from selenium produced in Canada and Japan.

In their 1986 EIAR, the AFIA estimates that the total environmental introductions of selenium that result from the current practice of selenium supplementation of animal diets in the entire U.S. is about 22.6 metric tons/yr. They also estimate that the new uniform level of 0.3 ppm selenium supplementation of animal diets would "on a worst case basis" result in a doubling of the expected environmental introductions in the U.S. to about 45 metric tons/yr. The proportion of total selenium consumption in the U.S. that is represented by the selenium supplementation of animal diets could therefore increase by about 3.5% (from the current 3.4% of total U.S. consumption of selenium to a projected 6.9% of total U.S. consumption of selenium).

Local Context:

In local environments, the most significant direct increases in selenium introductions are likely to be seen in agricultural soils amended with animal wastes from animals given selenium supplementation at 0.3 ppm in their diet. The absolute and relative amounts of selenium that could be introduced into the terrestrial environment were examined using the following animal and soil models.

A. Animal Models

The three most significant (i.e., largest) groups of food-producing animals in the U.S. that are given selenium supplementation are cattle, swine and poultry. Therefore, models of the use of selenium in these three species and the environmental introductions that would result from these uses should account for the major introductions due to selenium supplementation in the United States. Most of the selenium from this use should ultimately enter the terrestrial environment via the application to soil of excreta from selenium-supplemented animals. The probable range of selenium concentrations in animal excreta that could enter the terrestrial environment will be adequately covered by the use of the three estimates given below.

The EPA (1974) published a document that dealt with effluent limitations for a wide variety of animal feedlots. Data from that document were used to estimate the feed intake (and selenium input) and waste excreted (and selenium output) for beef cattle, swine and chickens raised under typical management conditions. These three species of animals reach market weight after different periods of time, however, as they will probably all be continuously supplemented with selenium, the relative concentrations of selenium in their respective wastes should be fairly constant.

1. Beef cattle: In 19-26 weeks, steers starting at about 270 kg reach an average market weight of 477 kg. Over that time period, the average steer is fed 9 kg feed/day and excretes 22 kg raw waste/day. The bulk of the raw waste excreted is made up of water drunk by the animal. Nine kg of feed

supplemented at 0.3 mg/kg results in 2.7 mg/head/day selenium intake due to supplementation. Assuming that, in the worst-case, essentially all of the selenium is excreted, the selenium concentration in wet cattle waste should be no higher than about 0.12 ppm (2.7 mg/22 kg = 0.12 mg/kg = 0.12 ppm).

2. Swine: In 23-25 weeks, feeder pigs weighing about 25 kg reach an average market weight of 100 kg. Over that time period, the average pig is fed 2.2 kg feed/day and excretes 3.5 kg of raw waste/day. That weight of feed supplemented at 0.3 mg/kg results in a daily selenium intake of 0.66 mg/head. Assuming that essentially all of the selenium is excreted, the selenium concentration in wet swine wastes should be no higher than about 0.19 ppm (0.66 mg/3.5 kg = 0.19 mg/kg = 0.19 ppm).

3. Poultry: In 6-8 weeks, chicks weighing about 5 g become marketable broilers weighing an average of 1.8 kg. Over that time period, the average bird is fed 0.064 kg feed/day and excretes 0.054 kg of raw waste/day. That weight of feed supplemented at 0.3 mg/kg results in a daily selenium intake of 0.019 mg/bird. Assuming that essentially all of the selenium is excreted, the selenium concentration in the wet poultry wastes should be no higher than about 0.36 ppm (0.019 mg/0.054 kg = 0.36 mg/kg = 0.36 ppm). Of these three models, note that the poultry excreta contains the highest concentration of selenium.

B. Soil Models

Animal manure is very often disposed of via direct incorporation into the soil as a fertilizer. The rates of manure use will vary depending upon several circumstances (e.g., soil type, manure type, rainfall, etc.). For the purpose of this assessment, the following maximum practical manure application rates/year were used (Fairbank, 1983; Fuller and Warrick, 1985).

	Manure Application Rates	
Manure Type	Tons/Acre	Metric Tons/Hectare
Cattle Wastes	15	33.7
Swine Wastes	10	22.5
Chicken Wastes	7.5	16.8

The top six inches (15.2 cm) of soil in a one acre plot of soil weighs about two million lbs (909,000 kg). Therefore, that depth of soil in a one hectare (ha) plot (ha = 2.47 acres) would weigh about 2.25 million kg. One metric ton = 1,000 kg (2,200 lbs).

The following three examples estimate: a) the total amounts of selenium that could be introduced into a part of the terrestrial environment from manure amendment, and b) the relative increase in concentrations of selenium that could result from this incorporation of manure into soils.

Example 1: Cattle wastes incorporated into soil at 33.7 metric tons/ha would result in a total of 4.04 g of selenium from supplementation being added to the top 15.2 cm of each hectare of soil (0.12 mg selenium/kg waste X 33,700 kg waste/ha = 4,044 mg selenium/ha = 4.04 g selenium/ha).

The relative concentration of selenium in the top 15.2 cm of soil amended with such cattle wastes would be increased by about 1.8 parts per billion (ppb = ug/kg; 4,044 mg selenium/2.25 million kg soil = 0.0018 mg/kg = 1.8 ug/kg = 1.8 ppb).

Example 2: Swine wastes incorporated into top soil at 22.5 metric tons/ha would result in a total of 4.28 g of selenium from supplementation being added to the top 15.2 cm of each hectare of soil (0.19 mg selenium/kg waste X 22,500 kg waste/ha = 4,275 mg selenium/ha = 4.28 g selenium/ha).

The relative concentration of selenium in top soil amended with such swine wastes would be increased by about 1.9 ppb (4,275 mg selenium/2.25 million kg soil = 0.0019 mg/kg = 1.9 ug/kg = 1.9 ppb).

Example 3: Chicken wastes incorporated into top soil at 16.8 metric tons/ha would result in a total of 6.05 g of selenium from supplementation being added to the top 15.2 cm of each hectare of soil (0.36 mg selenium/kg waste X 16,800 kg waste/ha = 6,050 mg selenium/ha = 6.05 g selenium/ha).

The relative concentration of selenium in top soil amended with such chicken wastes would be increased by about 2.7 ppb (6,050 mg selenium/2.25 million kg soil = 0.0027 mg/kg = 2.7 ug/kg = 2.7 ppb).

In the following section on environmental fate, these increases in soil selenium level will be compared to the background levels of selenium already present in soils. The overall movement (flux) of selenium into and out of such an amended soil will also be estimated. The flux of selenium into the other environments represents the potential levels of selenium that might be transferred from the terrestrial environment into the aquatic environment and into the atmospheric environment. Finally, in the environmental effects section, these levels of selenium will be compared to those known or expected to result in adverse effects upon organisms present in the environment.

Environmental Fate

The form and concentration of selenium in soils, water, the atmosphere, and the biota can vary greatly (Bennett, 1983; Eisler, 1985; EPA, 1986; Fishbein, 1983; Hodson et al., 1984; Medinsky et al., 1985; Robberecht and Von Grieken, 1982; Shamberger, 1983; Sharma and Singh, 1983; Wilbur, 1980 & 1983). The actual rates of selenium transfer between each of these diverse environmental components are very difficult to establish, as they vary by locality. The simplest manner to deal with this very complex issue is to attempt to model the selenium background and the diverse selenium inputs

and outputs from an example environmental compartment that could be most directly impacted by the supplementation of animal feeds with selenium (i.e., one hectare of soil amended with animal wastes).

There are indications that selenium taken up by organisms in the aquatic environment could, in unusual circumstances, have significant environmental effects (Eisler, 1985; Finley, 1985; Lemly, 1985 a & b; Ohlendorf et al., 1986; NCDNR&CD, 1986). Therefore, an extreme example of aquatic introductions of selenium from soils amended with high levels of animal wastes will also be considered.

Soil Example:

The maximum increase in soil selenium levels would occur from the amendment of top soil with poultry wastes at a rate of 16.8 metric tons/ha/yr. This results in an increase of topsoil selenium concentration of about 2.7 ug selenium/kg of soil/yr, or a total input of selenium from poultry waste disposal of about 6.05 g/ha/yr. These values need to be compared with the background levels of selenium already present in soil. Bennett (1983) states that 0.4 mg selenium/kg soil is a representative concentration of selenium in agricultural soils, as it is the geometric mean of the normal range of selenium in cultivated surface soils . That level of selenium in soils represents a total of almost 900 g of selenium in the top 15.2 cm of soil in a hectare of land (0.4 mg selenium/kg soil X 2.25 million kg/ha = 898,092 mg/ha = 898 g/ha). Therefore, the amount of selenium in a poultry waste amendment represents an annual increase of about 0.67% of the selenium already present in the top 15.2 cm (6") of an average agricultural soil in the U.S.

Several scientists make the argument that the selenium levels in soils are often low and therefore selenium supplementation of animal feeds (either directly in the feed, or as a spray on food and forage plants, or included as an additional component of fertilizers used on the soils for such food plants) has become more necessary recently because of declining levels of selenium in plants grown in many places in the world (Frost, 1984; Gissel-Nielsen, 1984; Korkman, 1984; Sharma and Singh, 1983; Wilbur, 1980 & 1983). There is a concern that the selenium levels in many soils are being depleted and that the selenium cycle is "running down" due to increases in plant production, increased soil leaching of selenium because of acid rain, and decreased availability of selenium to plants due to increased fertilizer uses (Frost, 1984; Gissel-Nielsen, 1984; Sharma and Singh, 1983).

In fact, soils in Scandinavia and New Zealand often require the direct addition of about 10 g of selenium/ha in their fertilizer applications. This use in Finland and New Zealand alone will result in the use of from about 10 to 25 metric tons of selenium/yr (Gissel-Nielsen, 1984; Korkman, 1984).

Therefore the relatively small increase in total selenium in agricultural soils due to animal manure amendment should have a minimal impact upon the levels of selenium already available for transport into other environmental compartments. It is possible that this addition to soils may even be considered to be beneficial in those soils which are (or could become) deficient in levels of selenium necessary for adequate plant selenium uptake.

The selenium level in any specific environmental compartment usually represents the balance reached between the level that is already there and the dynamic additions and deletions that are occurring over time. Below is a list of reasonable estimates of the background selenium level found in an average agricultural soil and the selenium flux (inputs and outputs) that could result due to: a) soil amendment with manure, b) rainfall, c) direct deposition onto soil, d) volatilization from soil, e) runoff from rainfall, and f) harvesting of crops grown in this soil.

Selenium Flux in an Example Waste-Amended Soil

1. Background: 900 g selenium/ha (Bennett, 1983).

2. Inputs: Total = 9.4 g selenium/ha/yr.
   a. Amendment = 6.0 g selenium/ha/yr (poultry model).
   b. Rainfall = 1.3 g selenium/ha/yr; 25" rain/yr with 0.2 ppb selenium (Hodson et al., 1984; Robberecht & Von Grieken, 1982).
   c. Deposited = 2.1 g selenium/ha/yr; air (dry) deposition rate of 1.3 ng/m^3 (Bennett, 1983).

3. Outputs: Total = 2.1 g selenium/ha/yr.
   a. Volatilize = 0.8 g selenium/ha/yr; average of spring rate and fall rate (Zieve & Peterson, 1981).
   b. Runoff = 0.3 g selenium/ha/yr; 25% of selenium in rainfall on soil runs off (Hodson et al., 1984.)
   c. Harvest = 1.0 g selenium/ha/yr; average of corn at 6,300 kg/ha (100 bushels/acre, 56 lbs/bu) and wheat at 4,000 kg/ha (50 bushels/acre, 70 lbs/bu). Mean selenium concentration in terrestrial plants of 0.2 mg/kg (Wilbur, 1980 & 1983).

Therefore, for this example, the overall selenium inputs are larger than the selenium outputs by about 7.3 g/ha/yr. This would mean that, on average, the selenium levels in this soil would tend to increase by about 0.8% per year, a level that does not seem to be very significant.

The selenium outputs from this soil to the atmosphere and to the aquatic environment also do not appear to be very significant.

Aquatic Example:

Pesticides which are incorporated into soil may show seasonal losses to runoff of about 0.5%, however, these losses "can increase three-fold if runoff occurs within 2 weeks after application." (Willis and McDowell, 1982).

A worst-case example of possible selenium introductions into aquatic systems from soils freshly amended with manure will illustrate the maximum additional levels of selenium attributable to the waste amendment that can be expected to enter the aquatic environment. Assume that a large runoff event (4" rain with 2" of runoff) occurs shortly after poultry excreta has been incorporated into the soil of a 10 ha watershed at the maximum practical application rate. Assume further that a range of from 1 to 10% of the total selenium in this excreta is carried in the runoff from this 10 ha watershed into a one ha farm pond that is two meters (6.5') deep. The maximum additional selenium concentration in the runoff or in the farm pond would be about 1.2 ppb or 0.24 ppb (ug selenium/kg water), respectively. This is the concentration that would be added to selenium naturally present in the runoff and ponds at that locality.

Calculation

Given:

Maximum total selenium from excreta = 6.05 g/ha = 60.5 g/10 ha watershed.
Two inches rain runoff = 507,800 kg/ha = 5.08×10^6 kg/10 ha watershed.
One ha pond 2 m deep = 20 million liters water = 20×10^6 kg/ha pond.
Total water in pond (including 2" runoff) = 25.08×10^6 kg

Case 1: Selenium concentration range in runoff.

a) 60.5 g selenium/10 ha X 1% = 0.605 g = 605 mg selenium
605 mg selenium/5.08×10^6 kg runoff = 0.00012 mg/kg = 0.12 ppb

b) 60.5 g selenium/10 ha X 10% = 6.05 g = 6,050 mg selenium
6,050 mg selenium/5.08×10^6 kg runoff = 0.0012 mg/kg = 1.2 ppb

Case 2: Selenium concentration range in pond (after runoff dilution).

a) 1% of selenium from 10 ha watershed = 605 mg selenium
605 mg selenium/25.08×10^6 kg water = 0.000024 mg/kg = 0.02 ppb

b) 10% of selenium from 10 ha watershed = 6,0500 mg selenium
6,050 mg selenium/25.08×10^6 kg water = 0.00024 mg/kg = 0.24 ppb

These two cases assumed that the rainfall and the pond water were initially selenium free. In fact, natural environmental waters demonstrate a wide range of levels of selenium.

In unusual circumstances, selenium concentrations of from 10 ppb to 300 ppb in surface waters have been reported (Eisler, 1985; Lemly 1985a & b; Ohlendorf-et al., 1986; NCDNR&CD, 1986). However, the selenium concentrations in most lakes and rivers are 1 ppb or less (Adams and Johnson, 1981; Shamberger, 1983). Adams and Johnson (1981) report that samples from the Illinois, Missouri, and the Mississippi Rivers ranged from 0.3 to 1.0 ppb and averaged 0.6 ppb selenium. Wilbur (1980 & 1983) states that major rivers average about 0.2 ppb selenium, that the mean value for major U.S. drainage basins is also 0.2 ppb, and that the selenium concentration in natural waters averages about 0.25 ppb. From a survey of selenium in freshwater, Bennett (1983) reports that the range and median concentrations of selenium were 0.02-1 ppb and 0.2 ppb, respectively. Hodson and Hilton (1983) said that the typical selenium concentrations in surface waters was <0.1-0.4 ppb.

The above worst-case calculations of introductions of selenium from a 10 ha watershed into a pond indicate that the levels of selenium that might be added to natural waters are around the average levels that are already likely to be found in such waters. These levels of selenium are nowhere near those demonstrated to be an acute or chronic toxicity problem to organisms living in the aquatic environment (see below).

Environmental Effects

Terrestrial Environment:

There would appear to be little or no environmental concern about the relatively small additional introductions of selenium to the terrestrial environment that would occur as a result of selenium supplementation of animal diets. The levels anticipated would most probably not significantly affect terrestrial organisms (Eisler, 1985; Sharma and Singh, 1983; Wilbur, 1980 & 1983). The forms of selenium found in animal raw wastes have been reported to be essentially unavailable to plants (Frost, 1984; NRC, 1983; van Dorst and Peterson, 1984). In part, this may be due to the strong binding of some forms of selenium to soils (Gissel-Nielsen, 1984; Sharma and Singh, 1983; van Dorst and Peterson, 1984; Wilbur, 1980 & 1983).

Aquatic Environment:

Research has been reported recently on: a) selenium deficiency in aquatic animals (Eisler, 1985; Hodson and Hilton, 1983; Keating and Dagbusan, 1984; Winner, 1984), b) the dynamics of selenium uptake and loss by aquatic organisms (Bennett et al., 1986; Eisler, 1985; Hilton et al., 1982; Hodson et al., 1984; Kleinow and Brooks, 1986 a & b; Lemly, 1982), and c) the acute and chronic toxicity of selenium to a variety of aquatic organisms (Adams and Johnson, 1981; Dunbar et al., 1983; EPA, 1986; Eisler, 1985; Halter et al., 1980; Hodson et al., 1984; Klaverkamp et al., 1983; Lemly, 1985 a & b; NCDNR&CD, 1986; Reading and Buikema, 1983; Sato et al., 1980;

Sorensen et al., 1984; Ward et al., 1981). Most of these research articles indicate that the levels of selenium that could be introduced into the aquatic environment by the use of selenium supplementation of animal foods are very unlikely to result in any effects upon aquatic organisms.

The major area of concern about the environmental effects of selenium appears to focus on possible adverse impacts upon fish and wildlife that live in or near aquatic environments that are contaminated with high levels of selenium (Baumann and May, 1984; Eisler, 1985; Lemly, 1985 a & b; Ohlendorf et al., 1986; Sorensen et al., 1982 & 1984).

The items that are the most significant in this issue center upon: a) the extent of selenium bioconcentration and bioaccumulation that occurs in the aquatic environment, and b) the significance of these selenium residues to animals eating aquatic species from this environment. There continues to be considerable scientific controversy about the issue of selenium bioconcentration and bioaccumulation.

1. "There is no bioaccumulation of selenium in the food chain" (Gissel-Nielsen, 1984).
2. "There seems to be no evidence for biomagnification of selenium by aquatic organisms" (Wilbur, 1980).
3. "The biological half-life for Se in mammals is only a few weeks, which excludes the risk of bioaccumulation" (Sharma and Singh, 1983).
4. "The concentration factor of selenium by carp...was not large" (Sato et al., 1980).
5. "The accumulation of selenium by aquatic organisms is highly variable" (Eisler, 1985).
6. "The uptake of selenium by invertebrates and fish through the food chain is a cause for concern" (Brooks, 1984).
7. "Selenium can accumulate and be biologically magnified to toxic levels in a reservoir even though waterborne concentrations are in the low microgram per liter range" (Lemly, 1985a).
8. "Selenium is highly bioconcentrated by aquatic organisms and is biomagnified in aquatic food chains" (Lemly, 1985b).

The dichotomy evident in this issue is probably somewhat related to the focus of each of these researchers. In a broad context (i.e., nationwide), a good case can be made that: a) the selenium levels in many U.S. feeds are inadequate for good animal nutrition (Frost, 1984; Morris et al., 1984; Wilbur, 1980 & 1983), and b) the average selenium levels in fish in the U.S. from 1972 to 1980 did not increase (increases would be expected from the potential for selenium bioaccumulation by fish) and may even have decreased (May and McKinney, 1981; Baumann and May, 1984).

In a local context, it is evident that there are some parts of the U.S. that have experienced and could continue to experience selenium excesses. Baumann and May (1984) found in a nationwide survey of fish in the U.S. that the selenium levels in freshwater fish had not increased from 1972 to 1980. However, the survey did find fish from some locations having

unusually high selenium concentrations (the lakes and reservoirs draining areas of high selenium rock and soil or that were subject to large selenium influx from coal ash pond effluents).

The use of selenium as a supplement for animal feeds that are deficient in that element would be unlikely to result in any significant effects upon organisms in the environment. However, accidental misuses of selenium in animal feeds have occasionally resulted in toxicity to animals given this diet (Casteel et al., 1985; Harrison et al., 1983; Wilson et al., 1983). The individuals making decisions about selenium supplementation need to be aware not only of the possible dangers to the animals supplemented, but also the possible danger to any aquatic environments that may already be experiencing excess levels of selenium.

Conclusion

Selenium is a unique element. In small quantities, selenium is essential to life. In larger quantities, selenium causes toxic effects. Selenium can be in many chemical forms in the environment, some of which are bioavailable and accumulated in biota. However, many chemical forms of selenium are unavailable as a selenium source to biota. Selenium chemical forms cycle from bioavailable to unavailable forms and back as part of a worldwide biogeochemical cycle. Soil and rainfall acidity, soil oxygen concentration, microbial activity, soil cation exchange capacity and organic matter content, underlying geochemical composition and the quantity of rainfall all play important roles in determining whether selenium accumulates or is lost from soils. Man's activities, particularly through agriculture and the generation of acid rain, affect the equilibrium levels of selenium in soils. Intensive cropping, irrigation, and acid rain all tend to remove selenium from soil in the form of plant biomass and in runoff to surface waters. As a result, many animal feeds (and many human foods) produced in the United States are deficient in selenium. Other countries, for example Sweden and New Zealand, have similar deficiency problems which are being corrected by use of inorganic selenium in fertilizers.

Losses of selenium from soils to surface waters through runoff can also result in local excesses of selenium that, when water and sediment chemistry dictates, are bioavailable and accumulate in fish, aquatic plants, and waterfowl. The best known example of this problem is the Kesterson Reservoir in California. It is also probable that there are soils deficient in selenium within the Kesterson watershed.

The action being proposed in the AFIA food additive petition is to provide needed supplemental selenium, in a bioavailable form, to the feed of domestic animals. It is the Center for Veterinary Medicine's responsibility under the National Environmental Policy Act to determine whether approval of the food additive petition can be expected to cause significant environmental impacts.

This action is needed in large part because intensive agricultural practices deplete bioavailable selenium from soils at rates faster than it is deposited and recycled, resulting in plant materials that are deficient in selenium. When wastes from selenium-supplemented animals are amended into agricultural soils, man is, in effect, supplementing soils with selenium that may ultimately reduce the existing selenium deficiency. Selenium in animal wastes, however, is not initially in a bioavailable form. Local microbial activity and soil and rainwater chemistry determine the extent that selenium will be made bioavailable, sorbed to soil particles, or lost in runoff.

Undoubtedly, there are agricultural soils where additional selenium inputs are not needed. In these locations, it is important to monitor selenium content of soils and runoff to prevent local excesses. At the same time, any selenium contribution to these selenium sufficient soils from amendment of animal wastes would be proportionally very much smaller than the average situation addressed in the soil model above, and many of these locations could be safely amended with these wastes for years. Soil conservation and water runoff management programs also serve to limit the quantities of selenium lost from soils to the aquatic environment. Finally, it is not expected that animal feeds already sufficient in selenium will be routinely supplemented with additional selenium. Feed supplementation with selenium costs money and care must be taken by feed mixers to avoid uneven distribution of the supplement in the feed. Therefore, it is expected that selenium supplementation of feeds will be more limited in selenium sufficient areas than in deficient areas.

Selenium deficiency of soils and crops is a common and growing problem for much of the United States. Localized problems from selenium excess is a visible, but uncommon, occurrence. Management of selenium in the environment is increasingly important, due to the interference of man's activities in the biogeochemical cycling of selenium. This is a formidable challenge for landowners, soil conservationists and fish and wildlife managers.

AFIA's food additive petition attempts to address the selenium deficiency in animal feed problem. The action will indirectly help the selenium deficiency in soils and crops problems experienced in most of the United States. The increased supplementation levels of selenium in feeds that would be permitted under the AFIA petition is not expected to be a significant contributor to selenium excess problems experienced in certain localities. Due to the many biological, geological and chemical factors affecting selenium mobility in the environment, solutions to local selenium excess problems will probably have to be individually designed for each situation. Restrictions in the use of selenium-supplemented animal feed in particular locations may be a feature of individual local selenium management approaches. However, restrictions for localities as part of this food additive petition, in the absence of a local management plan, would be unlikely to be effective, perhaps be unnecessary, and is, furthermore, without legal precedent under the Federal Food, Drug and Cosmetic Act.

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11-28-86
Date

Preparer, HFV-152

12/1/86
Date

Primary Action Officer, HFV-220

11/28/86
Date

Chief, Environmental Staff, HFV-152

Attachments

Environmental Impact Analysis Report

A. Date: January 10, 1986

B. Name of applicant/petitioner: American Feed Industry Association, Inc.

C. Address: 1701 North Ft. Myer Drive
Arlington, Virginia 22209

D. Environmental information

1. Description of the proposed action:

a. Purpose of the action

To facilitate adequate and efficient selenium supplementation of animal feeds, the American Feed Industry Association (formerly American Feed Manufacturers Association) has petitioned the Food and Drug Administration (FDA) for revision of the current food additive regulation 573.920 - Selenium, which limits selenium supplementation of most animals to 0.1 ppm on a complete feed or ration basis and imposes unrealistic and overly burdensome controls.

Selenium is an essential trace element in animal nutrition. Major areas of the U.S. and crops grown thereon are deficient in selenium content. Other areas are marginal. Supplemental selenium is required to preclude feed deficiencies, and to maintain a normal food content of selenium. The selenium status of the United States is illustrated in the selenium map of the U.S. published in the Journal of Agricultural and Food Chemistry, (Kubota, 1967). A comparable map appears on Page 24 of the National Academy of Sciences' 1983 version of Selenium in Nutrition. This same publication states that selenium requirements for animals, on the basis of published information, will vary from 0.05 to 0.3 ppm - which exceeds the levels available from natural sources.

With the NAS publication identifying 0.3 ppm as the currently known highest requirement, this is the level requested to replace the maximum level of 0.1 ppm in the present regulation, and is expected to be the maximum level of supplementation. The substitution is expected to result in a general level of supplementation of 0.2 ppm - or a doubling of currently permitted maximum supplementation - to provide fully adequate dietary levels of selenium. Re-

placement of present unrealistic controls with more appropriate controls reflecting current good manufacturing practices for supplemental nutrients will provide needed flexibility in incorporating necessary supplemental selenium into feed in an efficient and economical manner.

The current food additive regulation (573.920-Selenium), as published in the April 1, 1985, Code of Federal Regulations, reads as follows:

§ 573.920 Selenium.

The food additive selenium may be safely used in accordance with the following prescribed conditions:

(a) The additive is used in animal feed as a nutrient in the form of sodium selenite or sodium selenate.

(b) It is added to feed as follows:

(1) Chickens: In complete feed at a level not to exceed 0.1 part per million.

(2) Swine:

(i) In complete feed (except prestarter ration and starter ration) at a level not to exceed 0.1 part per million.

(ii) In prestarter ration and starter ration at a level not to exceed 0.3 part per million.

(3) Turkeys: In complete feed at a level not to exceed 0.2 part per million.

(4) Sheep:

(i) In complete feed at a level not to exceed 0.1 part per million.

(ii) In a feed supplement for limit feeding at a level not to exceed an intake of 0.23 milligram per head per day.

(iii) Up to 30 parts per million in a salt-mineral mixture for free choice feeding at a rate not to exceed an intake of 0.23 milligram per head per day.

(5) Beef cattle:

(i) In complete feed at a level not to exceed 0.1 part per million.

(ii) In a feed supplement for limit feeding at a level not to exceed an intake of 1 milligram per head per day.

(iii) Up to 30 parts per million in a salt-mineral mixture for free choice feeding at a rate not to exceed an intake of 1 milligram per head per day.

(6) Dairy cattle: In complete feed (total ration) at a level not to exceed 0.1 part per million.

(7) Ducks: In complete feed (total ration) at a level not to exceed 0.1 part per million.

(c) The additive shall be incorporated into feed as follows:

(1) It shall be incorporated into each ton of the complete feed of chickens, swine (except prestarter ration and starter ration), sheep, beef cattle, dairy cattle, and ducks by a premix containing no more than 90.8 milligrams of added selenium and weighing not less than 1 pound.

(2) It shall be incorporated into each ton of the complete feed of turkeys by a premix containing no more than 181.6 milligrams of added selenium and weighing not less than 2 pounds.

(3) It shall be incorporated into each ton of salt-mineral mixture for sheep by a premix containing no more than 27.2 grams of added selenium in not less than 6 pounds of premix.

(4) It shall be incorporated into each ton of salt-mineral mixture for beef and dairy cattle by a premix containing no more than 18 grams of added selenium in not less than 4 pounds of premix.

(5) It shall be incorporated into each ton of prestarter ration and starter ration of swine by a premix containing no more than 272.4 milligrams of added selenium and weighing not less than 3 pounds.

(d) The premix manufacturer shall analyze each production batch of selenium premix and shall establish by such analysis that the levels of selenium specified in paragraph (c) of this section are not exceeded.

(e) The label or labeling of any selenium premix shall bear adequate directions and cautions for use including this statement: "Caution: Follow label directions. The addition to feed of higher levels of this premix containing selenium is not permitted."

The species and levels of use can be summarized as follows:

1. Chicken feeds - up to 0.1 ppm on a complete feed basis.
2. Turkey feeds - up to 0.2 ppm on a complete feed basis.
3. Duck feeds - up to 0.1 ppm on a complete feed basis.
4. Swine feeds - up to 0.1 ppm on a complete feed basis.
   - up to 0.3 ppm for young swine on a complete feed basis.
5. Sheep feeds - up to 0.1 ppm on a complete feed or ration basis, or
   - up to .23 mg/head/day
6. Dairy and beef feeds - up to 0.1 ppm on a complete feed or ration basis, or
   - up to 1 mg/head/day
7. Non-food Animals*- up to 0.1 to 0.2 ppm on a dietary basis, in line with good nutrition practice.

*FDA Policy per agreement with AFMA/AFIA.

The proposed regulation, by contrast, reads as follows:

Section 573.920 Selenium

The food additive selenium may be safely use in accordance with the following prescribed conditions:

(a) The additive is used in animal feed as a nutrient in the form of sodium selenite or sodium selenate.

(b) It is added to feeds as follows:

(1) Chickens: In complete feed, or on a complete feed basis, at a level not to exceed 0.3 part per million.
(2) Swine: In complete feed, or on a complete feed basis, at a level not to exceed 0.3 part per million.
(3) Turkeys: In complete feed, or on a complete feed basis, at a level not to exceed 0.3 part per million.
(4) Sheep:
(i) In complete feed, or on a total ration basis, at a level not to exceed 0.3 part per million.
(ii) In a feed supplement for limit feeding at a level not to exceed an intake of 0.7 milligram per head per day.

(iii) Up to 90 parts per million in a salt-mineral mixture for free choice feeding at a rate not to exceed an intake of 0.7 milligram per head per day.

(5) Beef cattle:

(i) In complete feed, or on a total ration basis, at a level not to exceed 0.3 part per million.

(ii) In a feed supplement for limit feeding at a level not to exceed an intake of 3 milligrams per head per day.

(iii) Up to 60 parts per million in a salt-mineral mixture for free choice feeding at a rate not to exceed an intake of 3 milligrams per head per day.

(6) Dairy Cattle:

(i) In complete feed, or on a total ration basis, at a level not to exceed 0.3 part per million.

(ii) Up to 60 parts per million in a salt-mineral mixture for free choice feeding at a rate not to exceed an intake of 3 milligrams per head per day.

(7) Ducks: In complete feed, or on a complete feed basis, at a level not to exceed 0.3 part per million.

(c) The additive shall be incorporated into feed as follows:

(1) It shall be incorporated into each ton of feed of chickens, swine, turkeys, sheep, beef cattle, dairy cattle, and ducks by a premix providing a level of selenium not exceeding that specified in Section (b) above and weighing not less than 1 pound.

(2) It shall be incorporated into each ton of salt-mineral mixture for sheep, and for beef and dairy cattle by a premix providing a level of selenium not exceeding that specified in Section (b) above for salt-mineral mixtures and weighing not less than 1 pound.

(d) The premix manufacturer shall follow good manufacturing practices in the production of selenium premixes. Inventory, production, and distribution records must provide a complete and accurate history of product production. Production controls must assure products to be what they are purported and labeled. Production controls shall include analysis sufficient to adequately monitor quality.

(e) The label or labeling of any selenium premix intended for direct addition to feed shall bear adequate directions and cautions for use including this statement: "Caution: Follow label directions. The addition of supplemental selenium to feeds must be in accordance with label directions. Higher levels of supplemental selenium may not be incorporated into feeds.

It is generally recognized that young and breeding animals have the greatest need for selenium. Hence, we expect feeds for these animals will be fortified in the 0.3 ppm level. Feeds for other animals are expected to be fortified at about the 0.2 ppm level. Supplementation will be highest in areas of known deficiency or borderline in nature, and less or not utilized in areas where selenium is not considered deficient in feeds.

In general, future use can be summarized as follows:

(1) Poultry (chicken, turkey, duck) feeds - up to 0.3 ppm on a complete feed basis.

(2) Swine feeds - up to 0.3 ppm on a complete feed basis.

(3) Sheep feeds - up to 0.3 ppm on a complete feed or ration basis, or up to 0.7 mg per head per day.

(4) Dairy and Beef feeds - up to 0.3 ppm on a complete feed or ration basis, or up to 3 mg per head per day.

(5) Minor food animals - In line with good feeding practices on same basis as major food animals above.

(6) Non-food animals - In line with good feeding practices on same basis as major food animals above.

Overall, we expect an average supplementation of about 0.2 ppm or equivalent. This is based on our contact with nutritionists in the feed industry. Thus, our best estimate is for a doubling of current use. The actual increase may be less in view of the current levels permitted for turkeys and young swine, and the treatment of deficiencies which should be prevented with higher levels of supplementation.

b. Environment to be affected

The environments potentially impacted by this action would be: selenium premix manutacturing sites, the feed mills where the selenium would be added, the farm areas where animals are kept and fed, the areas where the resultant animal wastes are stored and/or disposed of, the soils where such wastes are incorporated, and the aquatic environments into which selenium might leach from the animal wastes and/or soils where such animal wastes are deposited.

2. Probable impact

A comprehensive Environmental Impact Analysis Report was filed with the Bureau of Veterinary Medicine on July 31, 1972, under a cover letter to Director C. D. Van Houweling dated July 26, 1972. This "report" covered the possible effects of supplementation of chicken, turkey, and swine feeds. In the April 27, 1973, Impact Statement based on AFMA's Impact Report, it was concluded that supplementation of feeds would not have an adverse impact on the environment. Subsequent petitions to add sheep, cattle, layers, and ducks to the ranks of supplemented animals were accompanied by appropriate environmental reports. By far the most extensive, comprehensive report was the one entitled Environmental Assessment for Addition of Selenium to the Feed of Laying Hens, dated April 24, 1981, which stemmed from the 1979 petition for layers. A copy accompanies this petition.

As stated above, it is anticipated the use of supplemental selenium will, in general, double. Hence, twice as much selenium can be construed - on a worst case basis, to be introduced into the environment. Based on figures utilized in the series of previous reports, this would be an additional 22.6 metric tons of selenium - or a total of 45.2 metric tons. Total U.S. use was reported to be 618 metric tons (209 domestic plus 409 imported) in 1979, per the 1981 Environmental Assessment. Since domestic production is substantially less than need, any additional needs will have to be satisfied by imported material.

No adverse environmental impact is expected from the additional use of supplemental selenium in animal feeds. For detailed discussions of possible impacts, reference is made to the reports filed with the series of food additive petitions - particularly the 1981 Environmental Assessment. An appropriate doubling of levels utilized in these reports does not appear to present any significant concern.

3. Probable unavoidable adverse environmental effects

None believed to exist.

4. Alternatives to proposed action

As stated in the Environmental Assessment for Layers dated April 24, 1981 (see attached), the most practical method for correcting or preventing a selenium deficiency in poultry and livestock is the direct administration of supplemental selenium through their feed. (See page 30.) This is true of any nutrient needed on a routine basis. The only conceivable exception is range animals where a so-called selenium bullet deposited in the rumen may be more practical.

In discussing use of supplemental selenium in feed, the EA for Layers mentioned two potential problems. These were the mixing of the minute quantity required into feed and possible over formulation. In view of the industry's long experience with other micro nutrients and animal drugs, mixing was not expected to be nor has it been a problem. Neither has over formulation. Overall, there have been, to our knowledge, only two occasions of problems of any nature with selenium, and the Agency is aware of these instances.

Alternatives to feed supplementaion, as discussed in the EA for Layers, are soil amendment, interregional feed blending, corporeal injection, and feed monitoring (see pages 31-33). Each of these alternatives was discussed, with the individual and collective conclusion that feed supplementation was the only feasible route to follow in providing the required additional selenium (see pages 33-34).

5. Short-term use of environment and long-term productivity

The proposed action will be ongoing and "trade-off" is not a factor.

6. Irreversible/irretrievable commitment of resources

Selenium is the principle material in question. It is obtained as a byproduct of copper refining. (See pages 5-6.) Its use in animal feeds is a minor portion of total U.S. use. In 1976 it was estimated to be 22.6 metric tons of a total U.S. consumption of 618 metric tons. Doubling feed use to 45.2 metric tons and increasing total use to about 640.5 metric tons will result in feed use of some 7% of total use. Increased use will most likely come from increased imports, since domestic production is only about one-third of use (see page 5).

With respect to utilization of other natural, cultural, and energy resources in the U.S., any impact should be minimal since the source of additional material must lie outside the U.S. (See pages 28-29.) Hence, there is virtually no irreversible/irretrievable commitment of U.S. resources.

7. Objections

At this time, there are no known objections to supplying the nutritional requirement for selenium through feed supplementation.

8. Adoption of proposed action

The need for selenium supplementation in line with nutritional requirements is an existing fact. No adverse environmental impact is anticipated. Hence, adoption should not be delayed pending a draft or final impact statement.

9. Risk-benefit analysis

The facts that selenium is an essential nutrient and that most feed materials are deficient with respect to satisfying required amounts, coupled with no anticipated environmental impact, speak for themselves with respect to risk-benefit.

10. Certification

The undersigned applicant/petitioner certifies the information furnished in this Environmental Impact Analysis Report is true, accurate, and complete to the best of his knowledge.

January 10, 1986
Date

Signature of responsible official

Lee H. Boyd, Esq.
Vice President
American Feed Industry Association, Inc.
12th Floor
1701 N. Ft. Myer Drive
Arlington, Virginia 22209

Environmental Assessmept for the Addition of Selenium to the Feed of Laying Hens

1. Date: April 24, 1981

2. Name of applicant/petitioner: American Feed Manufacturers Association, Inc.

3. Address: 1701 N. Ft. Myer Drive
Arlington, Virginia 22209

4. Description of the proposed action:

The American Feed Manufacturer's Association (AFMA) has petitioned the Food and Drug Administration (FDA) for recognition of the addition of up to 0.1 ppm selenium (as sodium selenite or sodium selenate) to the feed of hens (on a complete feed basis) producing eggs for human consumption. AFMA has also requested removal of the provision limiting the feeding of supplemental selenium to growing chickens less than 16 weeks of age, that replacement pullets over 16 weeks of age can also receive supplemental selenium. Selenium is an essential trace element in animal nutrition. Major areas of the U.S. and crops grown thereon are deficient in selenium content. Other areas are marginal. Supplemental selenium is required to preclude feed deficiencies, and to maintain a normal food content of selenium. The selenium status of the United States is illustrated in the selenium map of the U.S. published in the Journal of Agricultural and Food Chemistry, (Kubota, 1967).

Layers are the only major food animal not presently approved to receive supplemental selenium in their diet. Swine, turkeys, and growing chickens have received supplemental selenium since January 1974. Ewes and young lambs have received it since March 1978. Supplemental selenium for all sheep, dairy cattle, and beef cattle has been approved since January 1979. Supplemental selenium has been considered appropriate and used in feeds for non-food animals since January 1974. Direct human supplementation comparable to levels for animals has been practiced for a number of years. Only layers and minor food animals, such as ducks and rabbits, are not presently approved for selenium supplementation.

The addition of layers to the approved ranks of animals will result in only a minimal increase in total use of supplemental selenium. The potential environmental effect will likewise be relatively minimal in nature.

Assuming that all feeds for laying hens located in selenium deficient areas (AFMA 1972), were to be supplemented with selenium in the form of sodium selenite, the result would be an additional selenium use of 1.03 metric tons. Supplementation of replacement pullet feeds from 16 weeks to onset of lay would require an additional 0.06 of a metric ton of selenium. This would be a total of 1.09 metric tons - or about 1.1 metric tons of selenium. This is approximately 5% of the estimated 21.5 metric

tons of selenium already used annually for the supplementation of feed for beef and dairy cattle, sheep, swine, turkeys and growing chickens. Thus, the incremental adverse impact on the environment should be negligible. Environmental benefits of this supplementation are the greater health and productivity of laying hens receiving supplemental selenium. This recently was pointed out in the October 1980 report of the Council on Agricultural Science and Technology (CAST) entitled, "Impact of Government Regulations on Development of Chemicals Used in Animal Production," which cites the delay in the approval of supplemental selenium for laying hens and uses selenium as a case study in its Attachment 3. The CAST report expands the earlier representations and projections which have been made regarding the benefits available from selenium supplementation.

The environments potentially impacted by this action would be: copper smelters, selenium premix manufacturing sites, the feed mills where the selenium would be added, the farm areas where the layers are kept and fed, the areas where the resultant chicken wastes are stored and/or disposed of, the soils where such wastes are incorporated, and the aquatic environments into which selenium might leach from the chicken wastes and/or soils where such chicken wastes are deposited.

5. Identification of chemical substances that are the subject of the proposed action:

(A) Description of the substance(s):

1) Common or usual name - Selenium. Common names of Selenium sources are -

a) Sodium Selenite, or

b) Sodium Selenate

2) Chemical names (as above)

3) Chemical Abstract Service (CAS) registry number (NIOSH, 1978)

a) Sodium Selenite is 10102-18-8

b) Sodium Selenate is 13410-01-0

c) Selenium (elements) is 7782-49-2

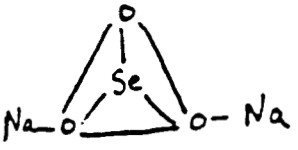
4) Empirical formula, molecular weight and physical description.

a) Sodium Selenite - Na_2SeO^3, 172.95, odorless white solid

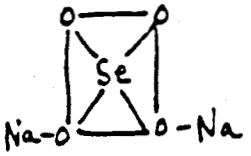
b) Sodium Selenate - Na_2SeO_4, 188.94, odorless white crystal

5) Structural formula -

a) Sodium Selenite



b) Sodium Selenate



6) Specifications for feed grade materials -

a) Sodium Selenite - commercial grade
b) Sodium Selenate - commercial grade

7) Typical quantitative compositions (AFMA, 1979)

a) Sodium Selenite		b) Sodium Selenate
Purity	99.9%	99.9%
Lead	.08%	.09%
Arsenic	None	None
Mercury	.0008%	.0008%
Cadmium	.008%	None

8) Other properties (NIOSH/OSHA unpublished)

	a) Sodium Selenite	b) Sodium Selenate
Boiling Pt (760 mm Hg):	decomposes	decomposes
Specific Gravity (H_2O = 1) :	3.1	3.1
Melting Pt.:	710°C decomposes	decomposes
Vapor Pressure (20°C) :	<0.001 mm Hg	<0.001 mm Hg
Water solubility (20°C) :	850g/liter	415g/liter

6. Introduction of substances into the environment:

Selenium is not mined alone, but is derived as a by-product from the precious-metal-rich anode slimes obtained from the electrolytic refining of copper. Three copper refineries in the U.S. recover selenium from materials of their own and from materials of other domestic and foreign plants (U.S. Bur. Mines, 1978). These three refiners are: 1) AMAX Copper, Inc. in Cartet, N.J.; 2) ASARCO Copper, Inc. in Amarillo, Texas; and 3) Kennecott Copper Co. in Magna, Utah. In 1978, domestic refiners produced about 209 metric tons of selenium (U.S. Bur. Mines, 1979). However, this only supplied about one-third of U.S. needs and an additional 409 metric tons were imported. Selenium supplementation of layer feeds apparently can be accomplished out of existing domestic and imported production of selenium.

The proposed action would increase the use of elemental selenium by up to 1.1 metric tons/yr., or a maximum of about 2.5 metric tons/yr of sodium selenite or sodium selenate is expected to be added to the diet of laying hens (AFMA, 1972) since these compounds are approximately 45% selenium by weight.

Sodium selenite and sodium selenate are the two chemical forms of selenium approved for use as a feed additive for several species of food-producing animals. Sodium selenite appears to be widely preferred for feed use over sodium selenate, as most of the nutritional research was done using sodium selenite. Sodium selenite also has a higher selenium content, while costing about the same as sodium selenate. Sodium selenite and sodium selenate are both manufactured at three plants in New Jersey: Atomergic Chemetals Corp. in Plainview; City Chem. Corp. in Jersey City; and, Fairmont Chem. Co., Inc. in Newark (Versar, 1975).

To prepare these compounds, elemental selenium is chemically treated with concentrated nitric acid to yield selenium dioxide and selenious acid. Selenium dioxide can then be dissolved in water and neutralized with sodium hydroxide to yield sodium selenite. Selenic acid is used to form selenates. Selenic acid is formed by using powerful oxidizing agents on selenium or selenious acid (Rosenfeld and Beath, 1964).

In 1976, the U.S. chemical and pharmaceutical industries were estimated to use about 67 metric tons (15%) of the total industrial selenium consumption for that year of about 450 metric tons (U.S. Dept. Commerce, 1978). On an annual basis, about one-third of this 67 metric tons (21.5 metric tons) was estimated to be used for addition to animal feeds (AFMA, 1972 and 1976). The proposed action will increase the maximum annual consumption of selenium in animal feeds by about 1.1 metric tons to a total of about 22.6 metric tons. There is no information available in the literature on discharges from the production of selenium-containing chemicals and pharmaceuticals.

Since it represents such a relatively small incremental increase in current selenium production, the proposed action probably would have no effect upon compliance with current emission requirements at production sites. The proposed action probably would also represent a minor addition to the total current emissions from sites of production, transport, use and disposal. (All phases from production of selenium through production and use of supplemented feed). The total environmental emissions of selenium in 1976 were estimated to be over 990, 1020 and 820 metric tons into the airborne, aquatic, and solid waste routes respectively (EPA, unpublished).

The proposed action might potentially result in effects in the environments of the following human and ecosystem components.

1. Workers in copper smelters
2. Workers in chemical and pharmaceutical/premix manufacturing plants
3. Workers in feed mills
4. Workers feeding animals
5. Air
6. Water
7. Soils
8. Solid Wastes

Following are identifiable Federal limits, criteria, and/or standards for selenium in various environments.

1. NIOSH/OSHA Draft Technical Standard for occupational exposures to selenium compounds -

   Permissible exposure - exposure of employees to airborne concentrations of selenium and inorganic compounds (as selenium) not in excess of 0.2 mg/m^3 of air, as averaged over an eight-hour work shift.

2. Public Health Service (PHS) Mandatory Upper Limit for selenium in drinking water -

   10 ppb

3. Environmental Protection Agency (EPA) Ambient Water Quality Criteria for selenium -

   a. To protect human health = 10 ppb

   b. To protect freshwater aquatic life = 35 ppb (as a 24 hr. avg., and concentration should not exceed 260 ppb at any time)

c. To protect saltwater aquatic life = 54 ppb (as a 24 hr. avg., and concentration should not exceed 410 ppb at any time)

4. EPA Solid Waste Criterion for selenium levels in sludges - >1.0 ppm of extractable Se requires listing as a hazardous waste.

Environmental Exposures

In general, Americans do not appear to be exposed to excessive levels of selenium in their food, water, air, or workplace. Human selenium intake is on the order of about 0.06 to 0.15 mg/day (Beliles, 1975) with the bulk of that probably coming from their diet. Selenium enters the food chain almost entirely via plants (NAS, 1976).

Selenium concentration in plants and animals depends largely on the concentrations and availability of selenium in the soil where the plants are grown. Morris and Levander (1970) took a cross section of the American diet and found the selenium content varied from about 0.01 to 0.50 ppm (wet weight). The 1976 National Academy of Science (NAS) report on Selenium concluded that "there seems no reason to expect either inadequacy or excess of the element [selenium] in our diets. . .." The NAS Food and Nutrition Board's Recommended Dietary Allowances (1980) sets an estimated safe and adequate intake range of

selenium for adult humans of 0.05 - 0.2 mg per day, or 50-200 ug per day. The 200 ug per day level is equivalent to the animal dietary level of 0.1 ppm. The NAS Board's Recommended Dietary Allowances further states that "Selenium intakes within the range of 50-200 ug/day can be obtained easily from a varied diet."

There are certain geographical areas which are selinferous and produce plants with high selenium content. Certain "indicator" plants have been found to concentrate extremely high levels of organic selenium. Occasionally livestock are forced to consume these plants and have developed diseases called "blind staggers" and "alkali disease" (NAS, 1976). Acute toxicity has resulted in animals consuming plants with high selenium levels (Burk, 1976). Whether selenium is responsible for this toxicity is open to question (Van Kampen and James, 1978). In contrast, geographic areas which are selenium deficient often result in plants with low selenium levels and animals fed diets from such plants - without supplementation - do not receive enough of this essential trace element in their diet (AFMA, 1972 and 1976).

The NAS (1976) reported that surface waters rarely contained selenium at levels above a few ppb. Water from wells in seleniferous areas and river waters containing irrigation drainage of seleniferous soils were sometimes found to have higher selenium levels.

The EPA (1975) reported only one sample out of 418 analyzed for Interstate Carrier Water Supplies in 1975 exceeded the 10 ppb drinking water limit. Craun et al. (1977) tested over 3,500 home tap water samples from residences in 35 geographically dispersed areas. They found less than 10% of these samples were above the minimum detection limit of 1 ppb and that the average of the mean selenium levels detected in the 35 areas was 3.82 ppb.

Most urban regions have aerial concentrations of particulate selenium ranging from about 0.1 to 10 ng/m^3 (NAS, 1976; Zoller and Reamer, 1976). The airborne levels of selenium do not contribute significantly to the overall human exposure levels (EPA, 1979). The vast majority of the selenium present in the air undoubtedly comes from the burning of coal and oil (NAS, 1976).

There is little information available on current actual exposure to selenium in the work environment. Proctor and Hughes (1978) briefly mention an older study of a selenium plant where workroom air levels ranged from 0.2 to 3.6 mg/m^3. This information was not confirmed in the article cited (Glover, 1970). In 1972, the United Nations International Labor Office (ILO, 1972) stated that "there have been no deaths or cases of irreversible pathological conditions due to selenium or its compounds in industry, agriculture or medical practice." While this report describes the potential hazards of working around selenium compounds, it

also states that "selenium compounds may be safely ingested by man in concentrations which, if ingested by animals would cause acute and chronic diseases and death."

In contrast with the foregoing, there was a report from Japan found "that increasing numbers of female workers in the manufacture of selenium rectifiers had irregular menses or menostasis" (NAS, 1976). This points out that the chronic effects of occupational exposures to selenium should be further monitored and current exposure levels determined.

7. Fate of emitted substances in the environment:

This action deals specifically with the use of sodium selenite or sodium selenate in laying hen feeds. The selenites and selenates, however, can be converted and/or metabolized into other selenium compounds (Figure 1), and the fate of the major selenium compounds will be briefly considered in this section. More comprehensive reviews on selenium fate can be found in NAS (1976) and Callahan et al. (1979).

Selenium is able to exist in the natural environment in four basic forms (oxidation states); as selenides (-2 state), as elemental selenium (0 state), as selenites (+4 state), and as selenates (+6 state). Which of these forms predominates depends upon the pH and redox potential of the environment (Callahan et al. 1979).

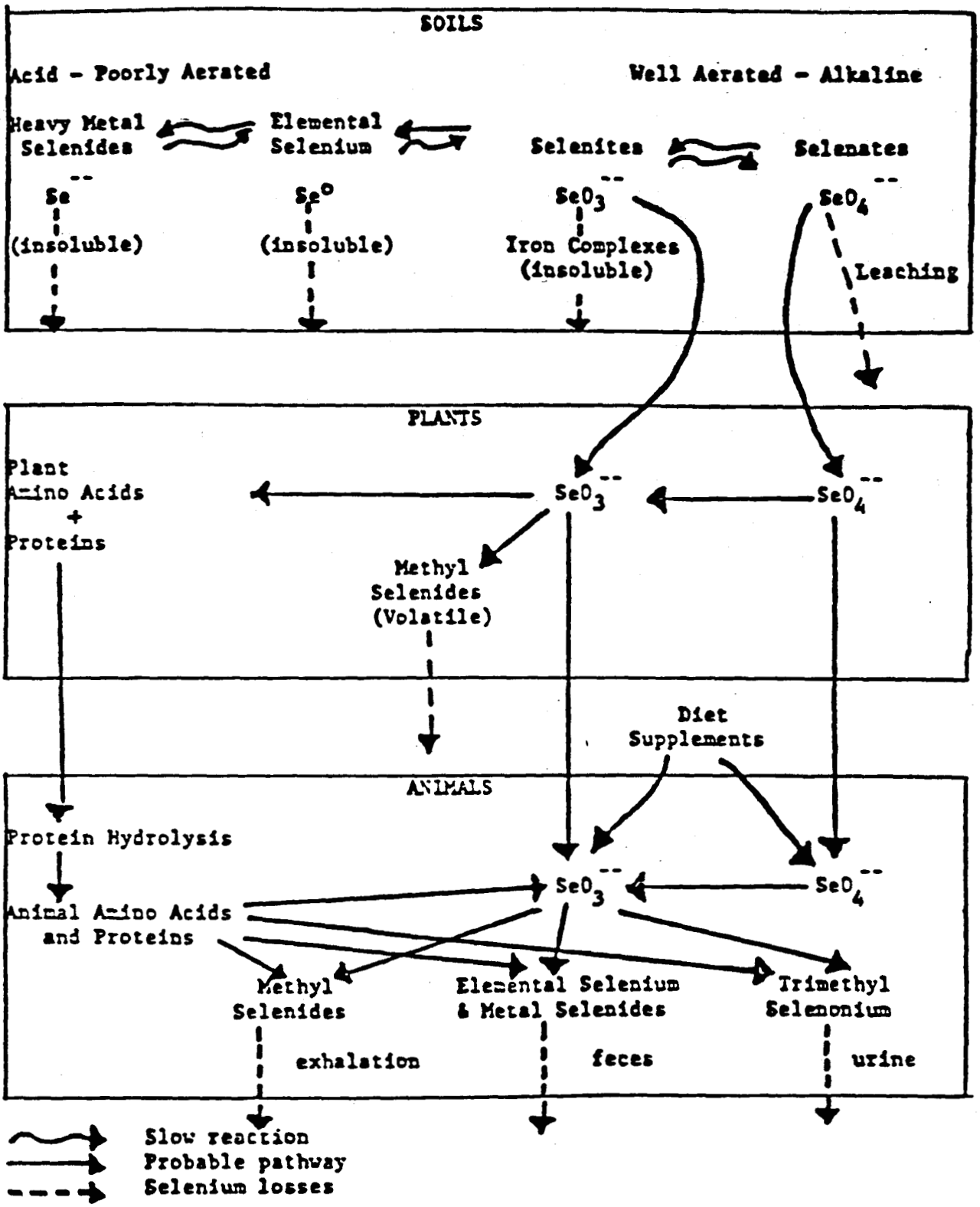


Figure 1 - Chemical and biochemical changes in selenium moving from soil through plants to animals. Adapted from NAS (1976).

Most selenides are very insoluble compounds that usually slowly decompose into elemental selenium. Elemental selenium is extremely insoluble in water, absorbs to sediments, and is generally non-toxic. These two forms of selenium are both fairly non-toxic and often end up in sediments as the major inert "sink" for selenium introduced into the environment (NAS, 1976).

Selenites are soluble in water and, in sandy soil, can be taken up by plants. However, under acidic conditions the selenites are often rapidly reduced in the environment to the relatively non-toxic and insoluble elemental selenium. Also selenites will quickly form insoluble absorbates with iron oxides. These characteristics, along with a relatively slow conversion to selenates under alkaline conditions, minimize the hazard of transport and environmental pollution by the selenites (NAS, 1976; Callahan et al., 1979).

Selenates are very soluble in water, stable at alkaline pH, and are also a readily available form for plant uptake. Soluble selenates are the form of selenium responsible for most naturally occurring instances of plants excessively accumulating selenium. These characteristics appear to make the selenates the form of selenium with the most potential for environmental pollution (Callahan et al., 1979). Fortunately, the selenates, which are usually present at lower levels and under acidic conditions, are often converted to other environmentally less dangerous forms of selenium.

When given as a dietary feed supplement to animals, sodium selenite was absorbed better from the gastrointestinal tract of monogastric animals than by ruminant animals (Wright and Bell, 1966). Such species differences are thought to be due to the reduction of the selenite to insoluble or unavailable forms by rumen microbes (NAS, 1976). When absorbed, the inorganic selenites and selenates can be metabolized and incorporated into protein materials, or may be excreted in various forms. Selenates are converted to selenites, which can be detoxified by metabolism to methyl selenides for elemination via exhalation, to elemental selenium and metal selenides for fecal excretion, and to trimethyl selenonium for urinary excretion (NAS, 1976).

The National Academy of Sciences (1976) concludes that "selenium present in fecal material apparently is not readily taken up by plants when the fecal material is applied to soil," as selenium conversion to the inert and insoluble forms is a significant feature of the soil-plant-animal system.

Microorganisms may also interact with selenium compounds in various manners. Selenite and selenate have been shown to be toxic to some yeast and bacteria, yet some microbe strains can adapt to high selenium conditions (NAS, 1976). Not only can rumen microbes degrade selenite to less toxic forms (NAS, 1976), but Chau et al. (1976) found that benthic microflora present in lake sediments could metabolize selenium compounds, including

sodium selenite and sodium selenate, by methylation to the volatile dimethyl selenide. Biomethylation and volatilization can remobilize selenium absorbed in sediments and might possibly result in significant selenium recycling (Callahan et al., 1979).

Worst Case Analysis - Soil, no leaching

The proposed action involves an annual feeding of a maximum of approximately 1.1 metric tons of supplemental selenium to laying hens and to replacement pullets over 16 weeks of age. This would result, if none of the selenium was retained or transmitted to eggs, in 1.1 metric tons of additional selenium being excreted into the fecal matter produced by these birds. Laying hens would account for most of the selenium, slightly over one metric ton. The manure will total some 4.85 million tons, or 4.40 million metric tons (AFMA, 1972).

The AFMA (1972) expected the average selenium concentrations in the wastes of selenium supplemented animals to be about 0.25 ppm. For a two week period, Latshaw and Osman (1975) fed laying hens a diet supplemented with 0.1 ppm of sodium selenate. The hens retained 68% of the selenium in the diet and the feces of these hens contained about 0.25 ppm of selenium. The forms of selenium present in the feces were not determined.

Based on the foregoing information, a metric ton of dry chicken waste from supplemented chickens may be expected to contain about 0.25 grams of selenium. Chicken droppings are expected to be added as a fertilizer to soil at a maximum practical application rate of about 4.6 metric tons/acre. This practice would add to the soil about 1.14 grams of selenium per acre (AFMA, 1972). Under normal farming practices, this chicken waste would be incorporated into the top six inches of soil. As this six inches of soil is estimated to weigh 909 metric tons (AFMA, 1972), the 1.14 g/acre of added selenium is equivalent to an increase in soil selenium content of 1.25 ppb.

The soils in selenium deficient areas are reported to contain 40 ppb selenium or less, and areas of moderate selenium content contain from 500 to 5,000 ppb of selenium (Allaway, 1968). Therefore the addition of these chicken wastes to selenium deficient soils could increase selenium levels by about 3%/yr, and could result in a small increase in soils already containing moderate levels of selenium. Addition of selenium to the deficient soils might have a beneficial impact by increasing the selenium levels in the crops grown in these regions.

In general, farmers apply animal wastes to the soil at the time of plowing in either spring or fall. Thus, as much as one year's production of waste could be stored in piles. However, laying hens are typically raised in totally housed systems and often

their manure will be allowed to accumulate indoors for a year or longer before the housing is cleaned and addition to soil occurs (White and Forster, 1978).

Worst case analysis - Water, complete leaching from soil

The area of the U.S. which will require selenium supplementation due to deficient levels in grains and feedstuffs comprises the eastern U.S. and west coast area of California, Oregon and Washington. The eastern U.S. is defined as the area east of the western borders of the following states: Minnesota, Iowa, Missouri, Arkansas and Louisiana. Of the states in the above described deficient areas, California has the lowest mean annual rainfall of 24 inches (Miller, 1973). Twenty-four inches of rainfall would be equivalent to 2,467,051 kilograms of water per acre (AFMA, 1972). Therefore, if the amount of selenium added by a maximum of 4.6 metric tons of dry layer waste (1.14 grams) is assumed to be totally leached out of the soil by the 24 inches of rainfall (2,467,051 kilograms), the result would be a selenium concentration of 0.46 ppb in the water. The average concentration of selenium for the waters of the entire area would be lower than this figure since the average rainfall of the other states is greater than California's and thus there would be further dilution. There would be additional dilution by rainfall and runoff from other areas not amended with selenium-containing wastes.

Bioaccumulation

Except for the few selenium accumulator plant species in specific seleniferous areas, the ability of selenium to bioaccumulate in the environment seems relatively small. Callahan et al. (1979) reviewed the aquatic literature and concluded that "the small amount of available data suggest that while dietary selenium is the most important source of selenium to many marine and freshwater organisms, little biomagnification takes place." Similarly, Cardwell et al. (1979) reviewed the aquatic literature and also suggested dietary pathways were more important than aqueous pathways in selenium bioaccumulation in aquatic organisms. Cardwell et al. (1979) also mentioned that relative to the heavy metals, field studies suggested that selenium accumulative potential was low.

The National Academy of Sciences report on selenium (1976) found that when animals were exposed to increasing amounts of selenium, the tissue levels of selenium tended to plateau with selenium being excreted faster at higher dose levels. This report concluded that "when animals are supplemented with nutritional amounts of inorganic selenium, there is little or no tendency for selenium to accumulate in the edible tissues of the animals above the levels that are known to occur in animals fed diets containing adequate quantities of naturally occurring selenium."

The FDA's concern about the environmental fate and bioaccumlation potential of animal feed additives containing selenium led to a contract (FDA Contract 223-74-8251) with Dr. Robert Metcalf (Univ. Illinois) to study the fate and bioaccumlation potential of sodium selenite in model ecosystems (Metcalf, 1976).

The model ecosystems were 10 gallon aquaria containing a terrestrial component of sand with sorghum growing in it, with the terrestrial part grading into an aquatic component of water containing algae, daphnia, snails, mosquito larvae and fish.

There were two selenium studies performed under this contract. In the first study, baby chickens were kept caged above the terrestrial part and given diets supplemented with 0.1 ppm of radioactively labeled sodium selenite. The labeled selenium was readily excreted from the chicks and entered the terrestrial and water phases of the model ecosystems. Some selenium was mobilized from the soil and water into the plants and animals, with plants storing relatively more selenium. Metcalf concluded however, that the data collected did <u>not</u> suggest any selenium food chain build up.

Using the same type of model ecosystems, but without using chickens, Dr. Metcalf performed a second study which compared the mobilization of radiolabeled sodium selenite from the terrestrial portions of model ecosystems containing sand or

sand amended with a silty clay loam soil. One ppb of sodium selenite was incorporated into the terrestrial part of the respective model ecosystems. The terrestrial portion of the model ecosystem with soil bound the sodium selenite much more tightly than did the terrestrial portion of the model ecosystem with sand only. Nevertheless, labeled selenium was mobilized from each system and some selenium accumulated in the biota of both model ecosystems.

Metcalf (1976) concluded that no food chain build up was seen, but he nevertheless speculated that sodium selenite "appears as a potentially dangerous environmental pollutant because it was readily excreted by animals" and was mobilized from soil and water into the plants and animals of his model ecosystems.

In contrast to Metcalf's speculation about potential pollution, the NAS report on selenium (1976) concluded that selenium use is probably not a significant pollution problem as only relatively small amounts of this element are introduced into the ecosphere, and this report also said that "the projected use of selenim as an animal feed additive is considered to have little potential for contributing to the burden of this element in the environment."

These two diverse points of view illustrate that even though the use of selenium as a feed additive is justifiable from a

nutritional viewpoint and in a broad (i.e. nationwide) context, potential local effects may be more pertinent to environmental assessment of this action. A consideration of both points of view seems appropriate, yet accurate information is often lacking on the environmental effects in the locations directly impacted by the proposed (and related) actions.

8. Environmental effects of released substances:

In acute tests, sodium selenite and sodium selenate are highly toxic at low doses. The amounts of these selenium compounds required to satisfy essential nutritional requirements for selenium, however, are only between one-tenth and one-hundredth the minimum toxic levels for animals (NAS, 1976), providing a safety factor of 10 to 100 fold. No significant adverse environmental effects are anticipated when animal waste containing selenium is incorporated into the soil at a rate of 4.6 metric tons or less per acre. Precautions should be taken in those instances where animal waste is stored in piles to ensure that the selenium leached by rainfall will not have direct access to the water table or other aquatic sources. Such storage, however, is not a common practice for layer waste. Adverse environmental impact in the form of increased selenium levels in the soil and water supply might occur if animal feeds were over-formulated by the addition of excess selenium or the addition of selenium to feeds already high in selenium.

The use of selenium as a feed additive should be carefully controlled to prevent harm to either the target animals or the environment. The FDA regulations on selenium supplementation of animal feeds were written in a fashion to reduce the possibility of this occurring (FDA, 1974).

1. Toxicology

a. Animal

The chronic and acute toxicities of various forms of selenium to laboratory animals and livestock have been reviewed previously (AFMA, 1972; NAS, 1976; Fishbein, 1977; EPA, 1979). Many factors enter into selenium toxicity, such as: (1) size and frequency of the doses; (2) characteristics of the compound; (3) presence of combining, reducing, diluting, or synergistic substances; (4) inherent susceptibility of the animal; and (5) efficiency of elimination after absorption (Muth and Binns, 1964).

The amount of supplemental selenium required to satisfy essential nutritional requirements of laying hens, which is 0.1 ppm, is about one-thirtieth of the minimum toxic level of about 3 ppm. Supplemental selenium for laying hens thus has a safety factor comparable to other micronutrients.

A variety of toxic effects are noted when excessive quantities (3-5 ppm over a sustained period) of selenium are ingested by livestock and poultry. Generally, these animals will suffer

from a loss of appetite, atrophy of the heart, cirrhosis of the liver and anemia.

In seleniferous areas, diets containing 5 ppm or more of selenium have been accepted as the dividing line between toxic and nontoxic feeds (NAS, 1976). Chronic selenium toxicity in livestock occurs when animals consume seleniferous plants containing 5-20 ppm of selenium over a prolonged period. Consumption of plant materials containing 400-800 ppm of organic selenium has been acutely fatal to sheep, hogs, and calves.

Toxic effects (up to and including lethality) of selenium can appear in livestock and chickens at dose levels of about 3-10 ppm in feed (AFMA, 1972; FDA, 1974; NAS, 1976; Fishbein, 1977; EPA, 1979). Therefore normal feeds (approximately 0.05-0.1 ppm selenium) that have in addition been supplemented with 0.1 ppm of selenium from sodium selenite or sodium selenate have a safety margin of about 20 to 50X for poultry and livestock. The fact that selenium from sodium selenite and sodium selenate is so toxic at high levels results in an environmentally beneficial side effect. If animals are accidentally over-dosed with selenium from either compound, the effects would be readily evident before significant quantities of selenium might be released or mobilized into the environment.

b. Human

Available animal data which have been extrapolated to effects on humans have been evaluated by the National Cancer Institute and the Food and Drug Administration (FDA, 1974). These data are summarized as follows: Selenium at high dietary levels (above 2 ppm) is a proven hepatotoxic agent. The evidence for carcinogenic effects at higher levels is inconclusive, but selenium at the nutritionally required levels was concluded not to be carcinogenic. In fact, recent evidence suggests that selenium may even be anticarcinogenic (NAS, 1976; Fishbein, 1977; EPA, 1979; Greeder and Milner, 1980).

Information concerning the potential toxicity of selenium in human diets in the United States has been collected and summarized by Smith and Westfall (1937), Williams et al. (1941), Trelease and Beath (1949), Hadjimarkos (1965), Frost (1972) and the National Academy of Sciences (1976). A review of these citations reveals no evidence that any people in the U.S. are exhibiting effects of toxic levels of selenium in food. Several investigators have provided evidence that elevated dietary selenium-levels may contribute to increases in dental caries (Hadjimarkos, 1965; Ludwig and Bibby, 1969; Buttner, 1963).

Public Health officials took action on the basis of reports that selenium may contribute to dental caries, on reports that the element is a potential carcinogen, and that concentrations of selenium in water considered safe for man were found toxic for fish. Their action took the form of lowering the previous standard for selenium in water from 50 ppb to 10 ppb (PHS, 1962).

c. Other Biota in the Environment

It is well-known that certain native plants growing on seleniferous soils accumulate high concentrations of selenium (Rosenfeld and Beath, 1964). In certain locations, accumulator species containing over 1,000 ppm of selenium have been found growing alongside grasses containing less than 10 ppm. These so-called selenium accumulator plants include 24 species and varieties of Astragalus (milk vetch); section Xylorhiza (woody aster) of Machaeranthera; section Oonopsis (goldenweed) of Haplopappus; and Stanleya (prince's plume). The accumulator plants generally grow in dry, nonagricultural areas which are unlikely to be fertilized with poultry manure, and range animals do not graze these areas unless forced to by a shortage of other feed.

Information with regard to the wildlife which feed on selenium accumulator plants is unavailable. Since these are noxious weeds which contain high levels of selenium, it is unlikely

that these plants would be preferred as a feed source for the indigenous fauna. Probably, the toxicity of selenium to wild herbivores would be of the same order of magnitude as that observed in domestic livestock and poultry.

Based upon the toxicity information and the estimates of selenium maximally entering the environment, the proposed action is unlikely to result in the mobilization of significant quantities of selenium for uptake by plants, and were this to happen in the anticipated selenium deficient areas, it would probably be beneficial.

Water supplies, even in seleniferous areas of the western U.S., have not been considered a potential source of human toxicity (EPA, 1979). The toxic effects of selenium on the aquatic biota have been reviewed by Rosenfeld and Beath (1964), FDA (1974), Metcalf (1976), EPA (1976 and 1979) and Cardwell et al. (1979). In the aquatic species tested, sodium selenite and sodium selenate in water were acutely to chronically toxic at concentrations ranging from approximately 2.5-10 ppm (or less), with some aquatic invertebrates and algae more sensitive than fish. In 1976, the EPA water quality criteria for selenium were set at 10 ppb for domestic water supplies (human health) and for marine and freshwater aquatic life at 1% of the 96-hour LC_{50} through bioassay of a sensitive resident species (EPA, 1976). These criteria were criticized as being

unsupported and too lenient by Cardwell et al. (1979). Based upon information that selenium can be accumulated to toxic concentrations by trophic levels below fish and that ingested selenium can kill fish at low concentrations, Cardwell et al. (1979) suggested water criteria of 0.1% of the 96-hour LC_{50} and a maximum selenium total water concentration of 50 ppb. The final EPA ambient water quality criteria for selenium (EPA, 1980) reviewed the literature and while it does not change the criterion for human health, the aquatic life criteria were changed. The criterion suggested to protect freshwater life is 35 ppb as a 24-hour average and is never to exceed 260 ppb. The suggested criterion to protect saltwater aquatic life is 54 ppb as a 24-hour average and should not exceed 410 ppb at any time.

Based upon the worst case analysis for leaching and the general lack of bioaccumulation ability of selenium, the proposed action seems unlikely to result in a situation where these criteria in water should be approached, let alone exceeded.

9. Utilization of natural and cultural resources and energy:

The energy required to produce 1 net ton of selenium powder is estimated to equal 297 million Btu (U.S. Bur. Mines, 1978). The proposed action is roughly estimated to increase current uses of selenium by up to 1.1 metric tons. This is a fraction of the 618 metric tons of selenium already used annually in the

U.S., two-thirds of which is imported (U.S. Bur. Mines, 1979). Therefore the impact upon utilization of natural and cultural resources and energy in the U.S. should be expected to be minimal.

10. Disruptions of the physical environment:

The nature and magnitude of this action seems unlikely to result in disruption of the physical environment as selenium is an element that will probably be reincorporated into the soil.

11. Mitigation measures:

To control potential adverse effects due to over-supplementation of feeds, the FDA food additive regulation governing selenium use in feeds stipulates that no more than one pound of a premix containing a maximum of 90.8 mg of selenium per pound may be added to a ton of complete type feed. At this premix concentration, 30 pounds of premix would have to be added to a ton of feed to reach a selenium level potentially toxic to chickens, a practice which is not expected to occur.

12. Alternatives to the proposed action:

Adverse environmental effects are not expected as a result of the proposed action and therefore alternatives to the action

need not be considered. Nevertheless, a description of possible alternatives will illustrate a need for the proposed action and practical approaches in implementing it.

The most practical method for correcting or preventing a selenium deficiency in poultry and livestock is the direct administration of supplemental selenium to the animals through their feed. Two potential problems are pertinent in evaluating the feed route as a means of administering physiologically effective quantities of selenium. The amounts required are so small (less than 1 ppm in the diet dry matter) that there can be a practical problem of adequate mixing with the large mass of feed material, and there is the possibility of over-formulation. These problems should be considered in any program of direct addition of selenium to animal feed. They were addressed in the provisions of the Food Additive Regulation for selenium which limits the potency of selenium premixes and the quantity of premix to be added to a ton of feed.

The alternative of not permitting the use of selenium would force livestock producers to rely on selenium obtained from natural sources. This alternative has been rejected since natural sources (feedstuffs and drinking water) often contain less than the needed amount of selenium. In 1972, the AFMA estimated a total annual loss to pullet and egg producers of $6.87 million because selenium was not used to supplement the diets of these birds.

There are several alternative ways in which selenium administration could be accomplished.

A. Soil Amendment

Selenium can be added to the soil on which our basic feedstuffs are grown. This practice has been successful in New Zealand since the 1960's, where farmers have applied 14-28g of selenium (as sodium selenite) per acre. Since the selenium-deficient arable area of the U.S. encompasses in excess of 509 million acres, this technique of selenium treatment would require the distribution of at least 7,000 metric tons of selenium. The entire proposed animal feed uses of selenium would involve only approximately 22.6 metric tons. From an environmental standpoint, therefore, dietary uses are more desirable, as that approach results in decreased energy uses and reduced distribution of selenium broadcast into the environment.

B. Interregional Feed Blending

Certain areas of the country produce basal feedstuffs which contain quantities of selenium at or above the required levels. Feedstuffs high in selenium content could be blended with those low in selenium to produce feedstuffs with adequate levels of selenium. This alternative has the advantage of not resulting in additional selenium introductions into the environment. There are several practical disadvantages to this alternative, 1) there probably are insufficient quantities of high selenium ingredients

to adequately balance the low selenium ingredients, 2) high selenium commodities would have to be identified and kept segregated in the marketplace, and 3) the extra costs (energy, etc.) associated with handling and transporting additional separate categories of bulky feed ingredients around the country would probably outweigh the intended economic benefit.

C. Corporeal Injection

This process would involve injecting animals with therapeutic levels of selenium. Its disadvantages accrue from the fact that each animal would have to be handled at periodic intervals and this would be a time consuming and costly procedure. As layers and pullets are of little individual value, economic reasons counteract any benefits and make this an infeasible alternative.

D. Feed Monitoring

This alternative would provide for the establishment of a program for monitoring the levels of selenium in the animal's diet through extensive and frequent chemical or physical analyses. Analytical methods that would be required for it are available. There are several acceptable methods published in the Journal of the Association of Official Analytical Chemists (A.O.A.C.). Several methods have been developed, including x-ray fluorescence spectrometry for the detection of potentially toxic levels of selenium and procedures for determining selenium in biological materials by neutron activation analysis.

Variations of this program would require individual feedmills to analyze either each ton of feed or each lot of feed ingredients prior to the addition of selenium. If each ton of feed were analyzed (maximum analysis costs $15-20 per sample), the analytical cost of the program alone would be a minimum of $170-228 million dollars (about 11 1/2 million tons of feed affected), a sum which probably would exceed the potential benefit. Furthermore, since most feed mills do not have the required laboratory facilities, outside laboratories would need to be utilized. This would add a burdensome time factor.

Conclusion: Of the four alternative methods discussed as satisfying the selenium requirements of laying hens, corporeal injection would involve the environmental distribution and use of about the same quantity of selenium as the proposed action. Rejection of corporeal injection was based on feasibility and cost considerations. The additional alternative of feed monitoring which could potentially limit selenium distribution was also rejected for excessive costs. The alternative of soil amendment was rejected since its application would require additional costs as well as the use of at least 300 times more selenium than that required by feed administration. (from 7,126 to 14,252 metric tons vs. 22.6 metric tons.) The alternative of inter-regional feed blending might be considered attractive

from an environmental viewpoint since no selenium salts would have to be distributed into the environment. However, the expansion of facilities and energy consumption required to accomplish the handling and movement of additional separate categories of feedstuffs would outweigh the proposed environmental benefits.

13. List of preparers:

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Maurice G. Zeeman, the preparer has been an environmental toxicologist in the FDA for one year where he assists in the analysis of the potential environmental impacts of actions proposed by applicants, petitioners, and the Agency, and in the evaluation of environmental documents prepared by other agencies. He specializes in toxicology and ecology and earned a M.A. in Zoology (Ecology) from U.C.L.A. in 1972 and a Ph.D. in Biology (Environmental Toxicology) from Utah State University, Logan, Utah in 1980.

Member: Society of Environmental Toxicology and Chemistry
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Sigma Xi - The Scientific Research Society
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Lee H. Boyd, the joint preparer, has served on the AFMA staff since 1960, with responsibilities for technical-scientific matters and regulatory compliance activities. Prior to joining AFMA, he had similar responsibilities for seven years with a midwest feed manufacturing firm. He received a B.A. in general science from Penn State in 1947, a B.S. in agriculture from Purdue in 1953, and a J.D. degree from Catholic University in 1979.

Mr. Boyd prepared the original petitions for selenium supplementation of animal feeds resulting in approval for swine, turkeys, and growing chickens. He was a member of the task force preparing subsequent petitions securing approval for sheep and for dairy and beef cattle. He is also the preparer of the pending petition for layers.

Member: American Registry Certified Animal Scientists
American Society Animal Science

14. Certification:

The undersigned certifies that the information presented is true, accurate, and complete to the best of his knowledge.

This 24th day of April, 1981

Signature of responsible official

Lee H. Boyd
Vice President
American Feed Manufacturers
Association

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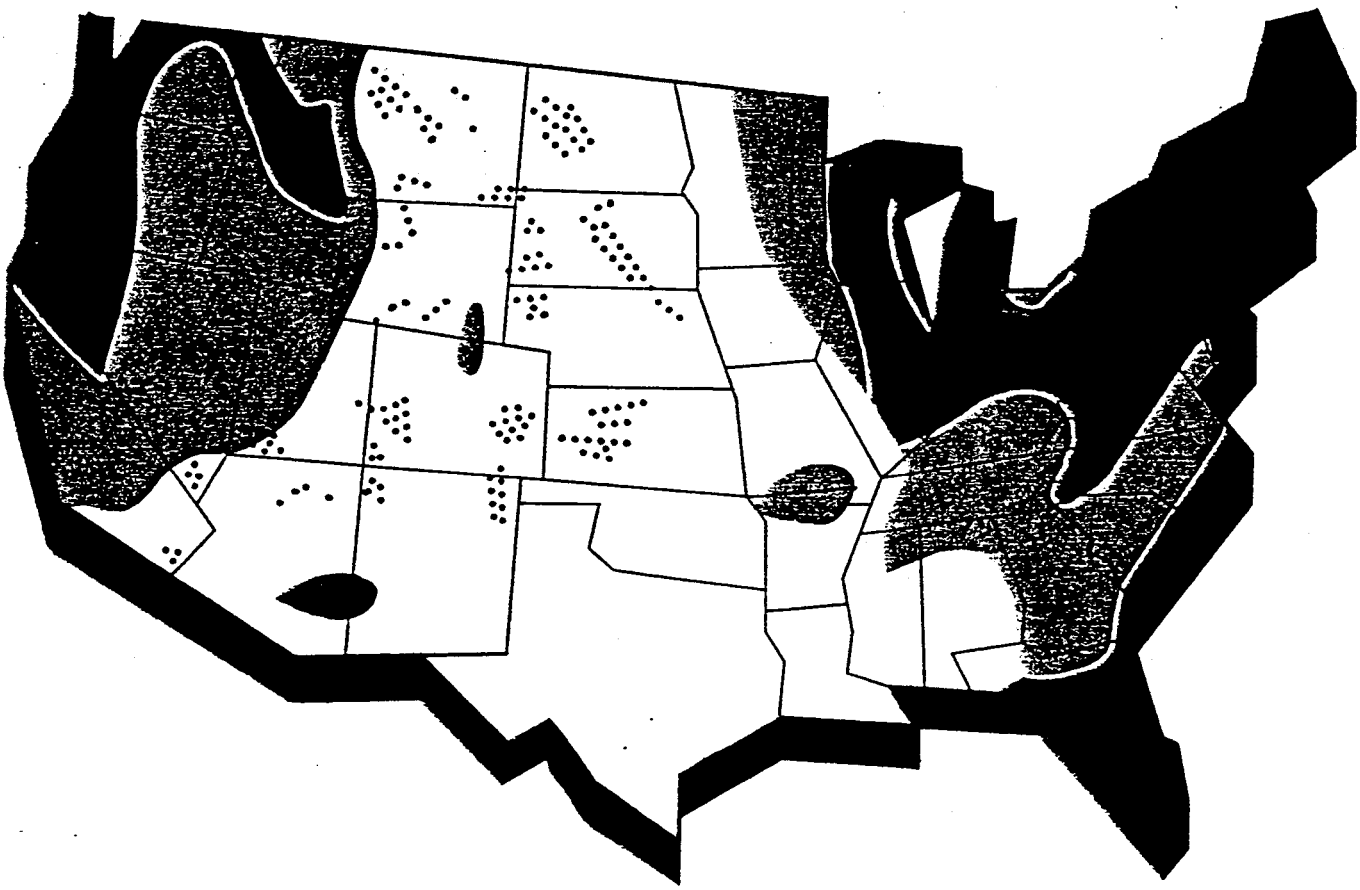
ATTACHMENT II

- U.S. Selenium Map, Kubota and Allaway, 1972

SELENIUM LEVELS IN THE UNITED STATES



Low area: approximately 80% of all forage and grain contains <0.05 ppm of selenium.

Variable area: approximately 55% contains >0.1 ppm of selenium.

Adequate area: 80% of all forage and grain contains >0.1 ppm of selenium.

Local areas where selenium accumulator plants contain >50 ppm.

Kubota and Allaway (1972)

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ATTACHMENT III

- Selenium Hazard Information Sheet
- MSDS - Selenium
- MSDS - Sodium Selenite
- Occupational Health Guidelines for Selenium and Its Inorganic Compounds

TO: Distribution

FROM: Yosepha Zarchin

SUBJECT: Selenium Hazard Information Sheet

DATE: June 18, 1985

The Material Safety Data Sheet accompanying this memo contains safety information on selenium. Please read it carefully and keep it on hand for reference. Sections to pay attention to include:

Section II - Hazardous Ingredients. Sodium selenite is both acutely toxic by ingestion and very irritating to the skin and eyes. When weighing or measuring powdered drugs outside the hood, latex gloves, safety glasses, and a dust respirator should be worn. When working in the hood, the mask is not necessary. Work surfaces should be covered with paper for ease in clean-up and decontamination. A bottle of neutralizing solution (10% sodium thiosulfate) should be kept on hand at all times.

Section V - Health Hazard Data. Since selenium is so irritating to skin and eyes, be certain you know the location of your eyewash, safety shower and neutralizing solution. In case of exposure, either skin, eye, ingestion, or inhalation, call 9-911 (outside emergency), 5333 (in-house emergency) and 5111 (plant maintenance - have me paged). When calling 9-911, be sure to give the building address -- 2631 Hanover Street -- and not just the building letter.

Section IX - Special Precautions. Although it is not mentioned in the MSDS, additional sources of information suggest that selenium may be teratogenic. As a precautionary measure, no women will be working on this project.

DISTRIBUTION:

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SECTION I - PRODUCT IDENTIFICATION

PRODUCT NAME: SELENIUM
FORMULA: SE
FORMULA WT: 78.96
CAS NO.: 07782-49-2
NIOSH/RTECS NO.: VS7700000
COMMON SYNONYMS: ELEMENTAL SELENIUM; SELENIUM DUST; SELENIUM HOMOPOLYMER
PRODUCT CODES: 3395

PRECAUTIONARY LABELLING

BAKER SAF-T-DATA(TM) SYSTEM

HEALTH - 3 (LIFE)
FLAMMABILITY - 0
REACTIVITY - 1
CONTACT - 2

LABORATORY PROTECTIVE EQUIPMENT

OGGLES; LAB COAT; VENT HOOD; PROPER GLOVES

PRECAUTIONARY LABEL STATEMENTS

WARNING
EXCEPTIONAL HEALTH HAZARD - READ MATERIAL SAFETY DATA SHEET
HARMFUL IF SWALLOWED OR INHALED
CAUSES IRRITATION
AVOID CONTACT WITH EYES, SKIN, CLOTHING.
AVOID BREATHING DUST. KEEP IN TIGHTLY CLOSED CONTAINER. USE WITH ADEQUATE VENTILATION. WASH THOROUGHLY AFTER HANDLING.

SECTION II - HAZARDOUS COMPONENTS

COMPONENT	%	CAS NO.
SELENIUM	90-100	7782-49-2

SECTION III - PHYSICAL DATA

BOILING POINT: 685 C (1265 F)
VAPOR PRESSURE(MM HG): N/A

MELTING POINT: 144 C (291 F)
VAPOR DENSITY(AIR=1): N/A

SPECIFIC GRAVITY: 4.81 (H2O=1)
EVAPORATION RATE: N/A (BUTYL ACETATE=1)

SOLUBILITY(H2O): NEGLIGIBLE (LESS THAN 0.1 %)
% VOLATILES BY VOLUME: 0

CONTINUED ON PAGE: 2

SECTION III - PHYSICAL DATA (CONTINUED)

APPEARANCE & ODOR: DARK GRAY TO DARK RED POWDER OR CRYSTALS.

SECTION IV - FIRE AND EXPLOSION HAZARD DATA

FLASH POINT: N/A

FIRE EXTINGUISHING MEDIA

USE EXTINGUISHING MEDIA APPROPRIATE FOR SURROUNDING FIRE.

SECTION V - HEALTH HAZARD DATA

THRESHOLD LIMIT VALUE (TLV/TWA): 0.2 MG/M3 (PPM)

TOXICITY: LD50 (ORAL-RAT)(MG/KG) - 6700
LD50 (IV-RAT) (MG/KG) - 6

EFFECTS OF OVEREXPOSURE

DUST MAY IRRITATE SKIN OR EYES.
DUST MAY IRRITATE NOSE AND THROAT.
PROLONGED EXPOSURE MAY CAUSE DERMATITIS.
INGESTION MAY CAUSE NAUSEA, VOMITING, HEADACHES, DIZZINESS, GASTROINTESTINAL IRRITATION.

EMERGENCY AND FIRST AID PROCEDURES

CALL A PHYSICIAN.
IF SWALLOWED, IF CONSCIOUS, IMMEDIATELY INDUCE VOMITING.
IF INHALED, REMOVE TO FRESH AIR. IF NOT BREATHING, GIVE ARTIFICIAL RESPIRATION. IF BREATHING IS DIFFICULT, GIVE OXYGEN.
IN CASE OF CONTACT, IMMEDIATELY FLUSH EYES WITH PLENTY OF WATER FOR AT LEAST 15 MINUTES. FLUSH SKIN WITH WATER.

SECTION VI - REACTIVITY DATA

STABILITY: STABLE HAZARDOUS POLYMERIZATION: WILL NOT OCCUR

INCOMPATIBLES: STRONG ACIDS, STRONG OXIDIZING AGENTS, MOST COMMON METALS

SECTION VII - SPILL AND DISPOSAL PROCEDURES

STEPS TO BE TAKEN IN THE EVENT OF A SPILL OR DISCHARGE

WEAR SELF-CONTAINED BREATHING APPARATUS AND FULL PROTECTIVE CLOTHING.
WITH CLEAN SHOVEL, CAREFULLY PLACE MATERIAL INTO CLEAN, DRY CONTAINER AND COVER; REMOVE FROM AREA. FLUSH SPILL AREA WITH WATER.

CONTINUED ON PAGE: 3

SECTION VII - SPILL AND DISPOSAL PROCEDURES (CONTINUED)

DISPOSAL PROCEDURE

DISPOSE IN ACCORDANCE WITH ALL APPLICABLE FEDERAL, STATE, AND LOCAL ENVIRONMENTAL REGULATIONS.

SECTION VIII - PROTECTIVE EQUIPMENT

VENTILATION: USE GENERAL OR LOCAL EXHAUST VENTILATION TO MEET TLV REQUIREMENTS.

RESPIRATORY PROTECTION: A RESPIRATOR WITH DUST/MIST FILTER IS RECOMMENDED. IF AIRBORNE CONCENTRATION EXCEEDS CAPACITY OF RESPIRATOR, A SELF-CONTAINED BREATHING APPARATUS IS ADVISED.

EYE/SKIN PROTECTION: SAFETY GOGGLES, UNIFORM, APRON, RUBBER GLOVES ARE RECOMMENDED.

SECTION IX - STORAGE AND HANDLING PRECAUTIONS

SAF-T-DATA(TM) STORAGE COLOR CODE: BLUE

SPECIAL PRECAUTIONS

KEEP CONTAINER TIGHTLY CLOSED. STORE IN SECURE POISON AREA.

SECTION X - TRANSPORTATION DATA AND ADDITIONAL INFORMATION

DOMESTIC (D.O.T.)

PROPER SHIPPING NAME	POISON B SOLID, N.O.S. (SELENIUM)
HAZARD CLASS	POISON B
UN/NA	UN2811
LABELS	POISON

INTERNATIONAL (I.M.O.)

PROPER SHIPPING NAME	SELENIUM METAL POWDER, NON-PYROPHORIC
HAZARD CLASS	6.1
UN/NA	UN2658
LABELS	HARMFUL - STOW AWAY FROM FOOD STUFFS

(TM) AND (R) DESIGNATE TRADEMARKS.
A = NOT APPLICABLE OR NOT AVAILABLE

THE INFORMATION PUBLISHED IN THIS MATERIAL SAFETY DATA SHEET HAS BEEN COMPILED FROM OUR EXPERIENCE AND DATA PRESENTED IN VARIOUS TECHNICAL PUBLICATIONS. IT IS THE USER'S RESPONSIBILITY TO DETERMINE THE SUITABILITY OF THIS INFORMATION FOR

CONTINUED ON PAGE: 4

THE ADOPTION OF NECESSARY SAFETY PRECAUTIONS. WE RESERVE THE RIGHT TO REVISE MATERIAL SAFETY DATA SHEETS PERIODICALLY AS NEW INFORMATION BECOMES AVAILABLE.

chemists helping chemists in research & industry

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ATTN: SAFETY DIRECTOR
ALZA CORPORATION
ACCOUNTS PAYABLE
P O BOX 10950
PALO ALTO CA 94303
N CKAFO

DATE: 07/14/86
CUST # 102261 P.O. # 52824 7U

MATERIAL SAFETY DATA SHEET

IDENTIFICATION

PRODUCT # 21448-5 NAME: SODIUM SELENITE, 99%
CAS # 10102-18-8

TOXICITY HAZARDS

RTECS # VS7350000
SELENIOUS ACID, DISODIUM SALT
TOXICITY DATA

ORL-RAT LD50:7 MG/KG	TXAPA9 20,89,71
IVN-RAT LD50:3 MG/KG	EQSSDX 1,1,75
ORL-MUS LD50:7 MG/KG	HYSAAV 35,176,70
IVN-MUS LD50:5 MG/KG	NRTXDN 2,383,81
ICV-MUS LD50:300 UG/KG	NRTXDN 2,383,81
ORL-RBT LD50:2250 UG/KG	HYSAAV 35,176,70
IMS-RBT LD50:2530 UG/KG	AXVMAW 30,627,76
ORL-GPG LD50:5060 UG/KG	HYSAAV 35,176,70

REVIEWS, STANDARDS, AND REGULATIONS
CARCINOGENIC REVIEW:ANIMAL INDEFINITE IARC** 9,245,75
OSHA STANDARD-AIR:TWA 0.2 MG(SE)/M3 FEREAC 39,23540,74
MSHA STANDARD-AIR:TWA 0.2 MG(SE)/M3 DTLVS* 3,224,71
NTP CARCINOGENESIS STUDIES; SELECTED, MARCH 1986
REPORTED IN EPA TSCA INVENTORY, 1983
EPA GENETIC TOXICOLOGY PROGRAM, JANUARY 1984
MEETS CRITERIA FOR PROPOSED OSHA MEDICAL RECORDS RULE FEREAC 47,30420, 82

HEALTH HAZARD DATA

ACUTE EFFECTS
MAY BE FATAL IF INHALED, SWALLOWED, OR ABSORBED THROUGH SKIN.
MAY CAUSE IRRITATION.
EXPOSURE CAN CAUSE:
NAUSEA, DIZZINESS AND HEADACHE
TO THE BEST OF OUR KNOWLEDGE, THE CHEMICAL, PHYSICAL, AND TOXICOLOGICAL PROPERTIES HAVE NOT BEEN THOROUGHLY INVESTIGATED.

FIRST AID
IN CASE OF CONTACT, IMMEDIATELY FLUSH EYES OR SKIN WITH COPIOUS AMOUNTS OF WATER FOR AT LEAST 15 MINUTES WHILE REMOVING CONTAMINATED CLOTHING AND SHOES.
IF INHALED, REMOVE TO FRESH AIR. IF NOT BREATHING GIVE ARTIFICIAL RESPIRATION, PREFERABLY MOUTH-TO-MOUTH. IF BREATHING IS DIFFICULT, GIVE OXYGEN.
IN CASE OF EXPOSURE, OBTAIN MEDICAL ATTENTION IMMEDIATELY.
WASH CONTAMINATED CLOTHING BEFORE REUSE.

PHYSICAL DATA

NO PHYSICAL DATA AVAILABLE

FIRE AND EXPLOSION HAZARD DATA

EXTINGUISHING MEDIA
NONCOMBUSTIBLE.
USE EXTINGUISHING MEDIA APPROPRIATE TO SURROUNDING FIRE CONDITIONS.

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Telex: 714838 Aldri D
FAX: (07329) 87-39

FORM 020 REV 2-86

MATERIAL SAFETY DATA SHEET PAGE: 2

CATALOG # 21448-5 NAME: SODIUM SELENITE, 99%

SPECIAL FIRE FIGHTING PROCEDURES
WEAR SELF-CONTAINED BREATHING APPARATUS AND PROTECTIVE CLOTHING TO PREVENT CONTACT WITH SKIN AND EYES.
UNUSUAL FIRE AND EXPLOSION HAZARDS
EMITS TOXIC FUMES UNDER FIRE CONDITIONS.

---------- REACTIVITY DATA ----------

INCOMPATIBILITIES
STRONG ACIDS
PROTECT FROM MOISTURE.
HAZARDOUS COMBUSTION OR DECOMPOSITION PRODUCTS
SELENIUM, SELENIUM OXIDES

---------- SPILL OR LEAK PROCEDURES ----------

STEPS TO BE TAKEN IF MATERIAL IS RELEASED OR SPILLED
EVACUATE AREA.
WEAR SELF-CONTAINED BREATHING APPARATUS, RUBBER BOOTS AND HEAVY RUBBER GLOVES.
SWEEP UP, PLACE IN A BAG AND HOLD FOR WASTE DISPOSAL.
AVOID RAISING DUST.
VENTILATE AREA AND WASH SPILL SITE AFTER MATERIAL PICKUP IS COMPLETE.
WASTE DISPOSAL METHOD
BURY IN A LANDFILL SITE APPROVED FOR THE DISPOSAL OF CHEMICAL AND HAZARDOUS WASTES.

OBSERVE ALL FEDERAL, STATE & LOCAL LAWS.

--- PRECAUTIONS TO BE TAKEN IN HANDLING AND STORAGE ----

WEAR APPROPRIATE OSHA/MSHA-APPROVED RESPIRATOR, CHEMICAL-RESISTANT GLOVES, SAFETY GOGGLES, OTHER PROTECTIVE CLOTHING.
SAFETY SHOWER AND EYE BATH.
USE ONLY IN A CHEMICAL FUME HOOD.
DO NOT BREATHE DUST.
DO NOT GET IN EYES, ON SKIN, ON CLOTHING.
AVOID PROLONGED OR REPEATED EXPOSURE.
WASH THOROUGHLY AFTER HANDLING.
HIGHLY TOXIC.
KEEP TIGHTLY CLOSED.
MOISTURE-SENSITIVE.
STORE IN A COOL DRY PLACE.

---------- ADDITIONAL PRECAUTIONS AND COMMENTS ---------

NOT APPLICABLE

THE ABOVE INFORMATION IS BELIEVED TO BE CORRECT BUT DOES NOT PURPORT TO BE ALL INCLUSIVE AND SHALL BE USED ONLY AS A GUIDE. ALDRICH SHALL NOT BE HELD LIABLE FOR ANY DAMAGE RESULTING FROM HANDLING OR FROM CONTACT WITH THE ABOVE PRODUCT. SEE REVERSE SIDE OF INVOICE OR PACKING SLIP FOR ADDITIONAL TERMS AND CONDITIONS OF SALE.

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Occupational Health Guideline for Selenium and Its Inorganic Compounds (as Selenium)*

INTRODUCTION

This guideline is intended as a source of information for employees, employers, physicians, industrial hygienists, and other occupational health professionals who may have a need for such information. It does not attempt to present all data; rather, it presents pertinent information and data in summary form.

APPLICABILITY

The general guidelines contained in this document apply to all selenium and its inorganic compounds. Physical and chemical properties of several specific compounds are provided for illustrative purposes.

SUBSTANCE IDENTIFICATION

Selenium

- Formula: Se
- Synonyms: Selenium, metallic; selenium, elemental
- Appearance and odor: Black, gray, or red odorless solid.

Sodium selenite

- Formula: Na_2SeO_3
- Synonyms: None
- Appearance and odor: Colorless and odorless solid.

Sodium selenate

- Formula: Na_2SeO_4
- Synonyms: None
- Appearance and odor: Colorless and odorless solid.

Selenium dioxide

- Formula: SeO_2
- Synonyms: None
- Appearance and odor: Colorless and odorless solid.

Selenium oxychloride

- Formula: $SeOCl_2$
- Synonyms: None
- Appearance: Colorless to yellow liquid.

PERMISSIBLE EXPOSURE LIMIT (PEL)

The current OSHA standard for selenium and its inorganic compounds is 0.2 milligram of selenium and its inorganic compounds (as selenium) per cubic meter of air (mg/m^3) averaged over an eight-hour work shift.

HEALTH HAZARD INFORMATION

- **Routes of exposure**

Selenium, sodium selenite, sodium selenate, or selenium dioxide can affect the body if they are inhaled, if they come in contact with the eyes or skin, or if they are swallowed. Selenium oxychloride and selenium dioxide may enter the body through the skin.

- **Effects of overexposure**

1. Short-term Exposure: Inhalation of large quantities of selenium dioxide or selenium oxychloride may cause severe breathing difficulties which may not appear for several hours after exposure. Skin contact with selenium dioxide or selenium oxychloride may cause skin burns. Skin exposure to selenium dioxide dust may cause a skin rash. Splashes of selenium dioxide may cause eye irritation. Selenium dioxide dust may cause "rose eye," an allergy of the eyelids in which they may become puffy.

2. Long-term Exposure: Prolonged exposure to selenium, sodium selenite, sodium selenate, or selenium dioxide may cause paleness, coated tongue, stomach disorders, nervousness, metallic taste and a garlic odor of the breath. Fluid in the abdominal cavity, damage to the liver and spleen, and anemia have been reported in animals. Prolonged skin contact with selenium oxide or selenium oxychloride may cause skin sensitization.

These recommendations reflect good industrial hygiene and medical surveillance practices and their implementation will assist in achieving an effective occupational health program. However, they may not be sufficient to achieve compliance with all requirements of OSHA regulations.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service Centers for Disease Control
National Institute for Occupational Safety and Health

U.S. DEPARTMENT OF LABOR
Occupational Safety and Health Administration

3. Reporting Signs and Symptoms: A physician should be contacted if anyone develops any signs or symptoms and suspects that they are caused by exposure to selenium and its inorganic compounds.

• **Recommended medical surveillance**

The following medical procedures should be made available to each employee who is exposed to selenium and its inorganic compounds at potentially hazardous levels:

1. Initial Medical Examination:

—A complete history and physical examination: The purpose is to detect pre-existing conditions that might place the exposed employee at increased risk, and to establish a baseline for future health monitoring. Persons with a history of asthma, allergies, or known sensitization to selenium, or with a history of other chronic respiratory disease, gastrointestinal disturbances, disorders of liver or kidneys, or recurrent dermatitis would be expected to be at increased risk from exposure. Examination of the eyes, respiratory system, liver, kidneys, and blood should be stressed. The skin should be examined for evidence of chronic disorders. Special consideration should be given to women of childbearing age since the possibility that selenium may be teratogenic might place these women in a high risk group.

—Urinalysis: Proper function of the kidneys is necessary to validate levels of selenium in the urine. A urinalysis should be obtained to include at a minimum specific gravity, albumin, glucose, and a microscopic on centrifuged sediment.

—Liver function tests: Selenium causes liver damage and tumors in animals. A profile of liver function should be obtained by using a medically acceptable array of biochemical tests.

2. Periodic Medical Examination: The aforementioned medical examinations should be repeated on an annual basis.

• **Summary of toxicology**

Elemental selenium and certain selenium compounds as dusts, vapors, and fumes irritate the eyes, upper respiratory tract, and skin. Animals exposed to selenium anhydride at a concentration of 150 mg/m^3 for 4 hours developed conjunctivitis, pulmonary edema, and convulsions preceding death; there were degenerative changes in the liver, kidneys, spleen, and heart. Prolonged feeding of animals with diets containing selenium in amounts of 5 to 15 ppm caused hepatic necrosis, hemorrhage, and cirrhosis; marked and progressive anemia occurred in some species. The possibility of teratogenic effects from exposure to selenium has been raised, based upon observations in animals, but it has not been established in man. Eleven of 53 rats developed adenoma or low-grade carcinoma in cirrhotic livers, and four others had advanced adenomatoid hyperplasia, after having survived for 18 to 24 months on diets containing 5, 7, or 10 ppm of selenium; no tumors occurred in 73 rats surviving less than 18 months, although after 3 months cirrhosis was frequent. In control rats 18 to 24 months of age, the incidence of spontaneous hepatic tumors was less than 1%. A group of workers briefly exposed to high concentrations of selenium fume developed severe irritation of the eyes, nose, and throat, followed by headaches; transient dyspnea occurred in one case. In workers exposed to an undetermined concentration of selenium oxide there was bronchospasm and dyspnea, followed within 12 hours by chills, fever, headache, and bronchitis, leading to pneumonitis in a few cases; all were asymptomatic within a week. In a study of workers in a selenium plant, workroom air levels ranged from 0.2 to 3.6 mg/m^3, while urinary levels ranged from below 0.10 to 0.43 mg/l; the chief complaints were garlic odor of the breath, metallic taste, gastrointestinal disturbances, and skin eruptions. An accidental spray of selenium dioxide, in unspecified form and concentration, into the eyes of a chemist caused superficial burns of the skin and immediate irritation of the eyes; within 16 hours vision was blurred, and the lower portions of both corneas appeared dulled; 16 days after the accident the corneas were normal. Acute burns of the skin can be caused by selenium oxychloride and selenium oxide, which are highly vesicant. Contact with the fume of heated selenium dioxide caused an acute, weeping dermatitis, with the development of hypersensitivity in some cases.

CHEMICAL AND PHYSICAL PROPERTIES

• **Physical data—Selenium**

1. Molecular weight: 78.96
2. Boiling point (760 mm Hg): 685 C (1265 F)
3. Specific gravity (water = 1): 4.45 to 4.8
4. Vapor density (air = 1 at boiling point of selenium): Not applicable
5. Melting point: 150 C (302 F)
6. Vapor pressure at 20 C (68 F): Less than 0.001 mm Hg
7. Solubility in water, g/100 g water at 20 C (68 F): Insoluble
8. Evaporation rate (butyl acetate = 1): Not applicable

• **Physical data—Sodium selenite**

1. Molecular weight: 173
2. Boiling point (760 mm Hg): Decomposes
3. Specific gravity (water = 1): 3.1
4. Vapor density (air = 1 at boiling point of sodium selenite): Not applicable
5. Melting point: 710 C (1310 F) (decomposes)
6. Vapor pressure at 20 C (68 F): Less than 0.001 mg Hg
7. Solubility in water, g/100 g water at 20 C (68 F): 85
8. Evaporation rate (butyl acetate = 1): Not applicable

• **Physical data—Sodium selenate**

1. Molecular weight: 188.9
2. Boiling point (760 mm Hg): Decomposes
3. Specific gravity (water = 1): 3.1

4. Vapor density (air = 1 at boiling point of sodium selenate): Not applicable

5. Melting point: Decomposes

6. Vapor pressure at 20 C (68 F): Less than 0.001 mm Hg

7. Solubility in water, g/200 g water at 20 C (68 F): 83

8. Evaporation rate (butyl acetate = 1): Not applicable

• **Physical data—Selenium dioxide**

1. Molecular weight: 110.9

2. Boiling point (760 mm Hg): 315 C (599 F) (sublimes)

3. Specific gravity (water = 1): 3.95

4. Vapor density (air = 1 at boiling point of selenium dioxide): Not applicable

5. Melting point: 340 C (644 F)

6. Vapor pressure at 20 C (68 F): 0.001 mm Hg

7. Solubility in water, g/100 g water at 20 C (68 F): 257

8. Evaporation rate (butyl acetate = 1): Not applicable

• **Physical data—Selenium oxychloride**

1. Molecular weight: 165.9

2. Boiling point (760 mm Hg): 176 C (349 F)

3. Specific gravity (water = 1): 2.42

4. Vapor density (air = 1 at boiling point of selenium oxychloride): 5.7

5. Melting point: 10.8 C (51 F)

6. Vapor pressure at 20 C (68 F): 0.35 mm approximately

7. Solubility in water, g/100 g water at 20 C (68 F): Decomposes

8. Evaporation rate (butyl acetate = 1): Not applicable

• **Reactivity**

1. Conditions contributing to instability: None hazardous

2. Incompatibilities: Contact of selenium with acids may cause formation of poisonous hydrogen selenide gas. Contact of selenium with strong oxidizing agents may cause fires and explosions.

3. Hazardous decomposition products: Toxic gases and vapors may be released in a fire involving selenium, sodium selenite, sodium selenate, selenium dioxide, and selenium oxychloride.

4. Special precautions: None

• **Flammability**

1. Flash point: Not applicable

2. Autoignition temperature: Selenium: Data not available; sodium selenite, sodium selenate, selenium dioxide, and selenium oxychloride: Not applicable

3. Flammable limits in air, % by volume: Not applicable

4. Extinguishant: For selenium, water

• **Warning properties**

The *Documentation of TLV's* notes that "Clinton reported intense irritation of eyes, nose, and throat, followed by headache, in a group of workers briefly exposed to high concentrations of selenium fume." The ILO reports that "persons who work in atmospheres containing selenium dioxide dust may develop a condition known among the workers as 'rose eye,' a pink allergy of the eyelids, which often become puffy. There is usually also a conjunctivitis of the palpebral conjunctiva but rarely of the bulbar conjunctiva." The *Hygienic Information Guide* for selenium states that "in contact with the eye, selenium compounds exert a rapid irritant action leading to inflammation." Grant reports that both selenium dioxide and selenium sulfide can produce toxic effects on the eye. Quantitative information concerning air concentrations of selenium compounds which cause eye irritation is not available.

MONITORING AND MEASUREMENT PROCEDURES

• **General**

Measurements to determine employee exposure are best taken so that the average eight-hour exposure is based on a single eight-hour sample or on two four-hour samples. Several short-time interval samples (up to 30 minutes) may also be used to determine the average exposure level. Air samples should be taken in the employee's breathing zone (air that would most nearly represent that inhaled by the employee).

• **Method**

Sampling and analyses may be performed by collection of selenium and its inorganic compounds on a filter, followed by treatment with acid and atomic absorption spectrophotometric analysis. An analytical method for selenium and its inorganic compounds is in the *NIOSH Manual of Analytical Methods*, 2nd Ed., Vol. 3, 1977, available from the Government Printing Office, Washington, D.C. 20402 (GPO No. 017-033-00261-4).

RESPIRATORS

• Good industrial hygiene practices recommend that engineering controls be used to reduce environmental concentrations to the permissible exposure level. However, there are some exceptions where respirators may be used to control exposure. Respirators may be used when engineering and work practice controls are not technically feasible, when such controls are in the process of being installed, or when they fail and need to be supplemented. Respirators may also be used for operations which require entry into tanks or closed vessels, and in emergency situations. If the use of respirators is necessary, the only respirators permitted are those that have been approved by the Mine Safety and Health Administration (formerly Mining Enforcement and Safety Administration) or by the National Institute for Occupational Safety and Health.

• In addition to respirator selection, a complete respiratory protection program should be instituted which

includes regular training, maintenance, inspection, cleaning, and evaluation.

PERSONAL PROTECTIVE EQUIPMENT

- Employees should be provided with and required to use impervious clothing, gloves, face shields (eight-inch minimum), and other appropriate protective clothing necessary to prevent any possibility of skin contact with selenium oxychloride or liquids containing selenium oxychloride.
- Employees should be provided with and required to use impervious clothing, gloves, face shields (eight-inch minimum), and other appropriate protective clothing necessary to prevent repeated or prolonged skin contact with selenium, sodium selenite, sodium selenate, or liquids containing these compounds.
- Employees should be provided with and required to use impervious clothing, gloves, face shields (eight-inch minimum), and other appropriate protective clothing necessary to prevent skin contact with selenium dioxide or liquids containing selenium dioxide, where skin contact may occur.
- If employees' clothing has had any possibility of being contaminated with selenium oxychloride, sodium selenite,sodium selenate, selenium dioxide, or liquids containing these compounds, employees should change into uncontaminated clothing before leaving the work premises.
- Clothing which has had any possibility of being contaminated with selenium oxychloride, sodium selenite, sodium selenate, or selenium dioxide should be placed in closed containers for storage until it can be discarded or until provision is made for the removal of contaminant from the clothing. If the clothing is to be laundered or otherwise cleaned to remove the contaminant, the person performing the operation should be informed of contaminant's hazardous properties.
- Where there is any possibility of exposure of an employee's body to selenium, selenium oxychloride, sodium selenite, sodium selenate, selenium dioxide, or liquids containing these compounds, facilities for quick drenching of the body should be provided within the immediate work area for emergency use.
- Non-impervious clothing which becomes contaminated with selenium, sodium selenite, sodium selenate, selenium dioxide or liquids containing these compounds should be removed promptly and not reworn until the contaminant is removed from the clothing.
- Non-impervious clothing which becomes contaminated with selenium oxychloride should be removed immediately and not reworn until the selenium oxychloride is removed from the clothing.
- Employees should be provided with and required to use dust- and splash-proof safety goggles where there is any possibility of selenium dioxide, selenium oxychloride, or liquids containing these compounds contacting the eyes.
- Employees should be provided with and required to use dust- and splash-proof safety goggles where sodium selenite, sodium selenate, or liquids containing these compounds may contact the eyes.
- Where there is any possibility that employees' eyes may be exposed to selenium oxychloride, selenium dioxide, or liquids containing these compounds, an eye-wash fountain should be provided within the immediate work area for emergency use.

SANITATION

- Workers subject to skin contact with selenium oxychloride, sodium selenite, sodium selenate, selenium dioxide, or liquids containing these compounds should wash any areas of the body which may have contacted selenium oxychloride, sodium selenite, sodium selenate, selenium dioxide, or liquids containing these compounds at the end of each work day.
- Skin that becomes contaminated with selenium, sodium selenite, sodium selenate, selenium dioxide, or liquids containing these substances should be promptly washed or showered to remove any contaminant.
- Skin that becomes contaminated with selenium oxychloride should be immediately washed or showered to remove any selenium oxychloride.
- Eating and smoking should not be permitted in areas where selenium oxychloride, sodium selenite, sodium selenate, selenium dioxide, or liquids containing these compounds are handled, processed, or stored.
- Employees who handle selenium oxychloride, sodium selenite, sodium selenate, selenium dioxide, or liquids containing these compounds should wash their hands thoroughly before eating, smoking, or using toilet facilities.

COMMON OPERATIONS AND CONTROLS

The following list includes some common operations in which exposure to selenium and its inorganic compounds may occur and control methods which may be effective in each case:

Operation	Controls
Liberation during mining recovery, and purification and manufacture of selenium compounds	Local exhaust ventilation; general dilution ventilation; personal protective equipment

Operation	Controls
Use in glassware industry for decolorization of fiberglass, scientific glassware, vehicular tail lights, traffic and other signal lenses, and infrared equipment; use in manufacture of electrical components in welding, transformers, semiconductors, photoelectric cells, etc.	Local exhaust ventilation; general dilution ventilation; personal protective equipment
Use in manufacture of photography and photocopy devices; manufacture of dyes, pigments, and colored glazes for metal etching and for printing on glass	Local exhaust ventilation; general dilution ventilation; personal protective equipment
Use in manufacture of lubricating oils and extreme pressure lubricants as antioxidants and detergency improvers	Local exhaust ventilation; general dilution ventilation; personal protective equipment
Use in rubber industry for manufacture and use as vulcanization accelerators and antioxidants; use in manufacture of pharmaceuticals, fungicides, and dermatitis control	Local exhaust ventilation; general dilution ventilation; personal protective equipment
Use as a catalyst for hardening fats for soaps, waxes, edible fats, and plastics	Local exhaust ventilation; general dilution ventilation; personal protective equipment
Use in manufacture of insecticides, parasiticides, bactericides, and herbicides for agricultural and citrus crops	Local exhaust ventilation; general dilution ventilation; personal protective equipment
Use in manufacture of flame-proofing agents on textiles and electric cables	Local exhaust ventilation; general dilution ventilation; personal protective equipment
Use in manufacture of delayed action blasting caps	Local exhaust ventilation; general dilution ventilation; personal protective equipment
Use as solvents in paint and varnish removers; rubber, resin, and glue solvent; use for organic synthesis in oxidation, hydrogenation, and dehyrogenation	Local exhaust ventilation; general dilution ventilation; personal protective equipment
Use in refining of copper, silver, gold, or nickel ores or during recycling of scrap metal	Local exhaust ventilation; general dilution ventilation; personal protective equipment
Use in miscellaneous operations in manufacture of insect repellants, activators, hardeners, special ceramic materials, plasticizers, and mercury vapor detectors	Local exhaust ventilation; general dilution ventilation; personal protective equipment
Use for preparation of feed additives for poultry and swine	Local exhaust ventilation; general dilution ventilation; personal protective equipment

EMERGENCY FIRST AID PROCEDURES

In the event of an emergency, institute first aid procedures and send for first aid or medical assistance.

- **Eye Exposure**

If selenium or its inorganic compounds get into the eyes, wash eyes immediately with large amounts of water, lifting the lower and upper lids occasionally. Get medical attention immediately. Contact lenses should not be worn when working with these chemicals.

- **Skin Exposure**

If selenium or its inorganic compounds get on the skin, immediately wash the contaminated skin. If selenium, sodium selenite, sodium selenate, or selenium dioxide soak through the clothing, remove the clothing immediately and wash the skin. If irritation persists after washing, get medical attention.

- **Breathing**

If a person breathes in large amounts of selenium sodium selenite, sodium selenate, or selenium dioxide, move the exposed person to fresh air at once. If breathing has stopped, perform artificial respiration.

Keep the affected person warm and at rest. Get medical attention as soon as possible.

• **Swallowing**

When selenium, sodium selenite, sodium selenate, selenium oxychloride, or selenium dioxide have been swallowed and the person is conscious, give the person large quantities of water immediately. After the water has been swallowed, try to get the person to vomit by having him touch the back of his throat with his finger. Do not make an unconscious person vomit. Get medical attention immediately.

• **Rescue**

Move the affected person from the hazardous exposure. If the exposed person has been overcome, notify someone else and put into effect the established emergency rescue procedures. Do not become a casualty. Understand the facility's emergency rescue procedures and know the locations of rescue equipment before the need arises.

SPILL AND DISPOSAL PROCEDURES

• Persons not wearing protective equipment and clothing should be restricted from areas of spills until cleanup has been completed.

• If selenium or its inorganic compounds are spilled, the following steps should be taken:

1. Ventilate area of spill.
2. Collect spilled material in the most convenient and safe manner and deposit in sealed containers for reclamation or for disposal in a secured sanitary landfill. Liquid containing selenium and its inorganic compounds should be absorbed in vermiculite, dry sand, earth, or a similar material.

• Waste disposal method:

Selenium and its inorganic compounds may be disposed of in sealed containers in a secured sanitary landfill.

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* SPECIAL NOTE

Selenium and its inorganic compounds (as selenium) appear on the OSHA "Candidate List" of chemicals being considered for further scientific review regarding their carcinogenicity (*Federal Register*, Vol. 45, No. 157, pp. 5372-5379, 12 August 1980).